

# **EXHIBIT A**

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**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

THE UNITED STATES OF AMERICA *ex rel.*  
RICHARD TEMPLIN AND JAMES  
BANIGAN, *et al.*

Plaintiffs,  
vs.

ORGANON USA INC., *et al.*,

Defendants.

Civil Action No. 07-12153-RWZ

**EXPERT REPORT OF KEVIN G. MCANANEY**

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EXPERT REPORT OF KEVIN G. MCANANEY

*United States ex rel. Banigan v. Organon USA Inc., et al.*  
Case No. 07-12153 – RWZ (D. Mass.)

**I. INTRODUCTION**

1. This is my expert report on the work that I have done to date in the course of my engagement as an expert witness for Omnicare, Inc. (“Omnicare”) in the above-referenced proceeding. I have been asked to provide my analysis and assessment of certain allegations made by Relators regarding the discounts and rebates (“Discounts and Rebates”) offered by Organon to Omnicare and four institutional pharmacies acquired by Omnicare (the “Acquired Pharmacies”)<sup>1</sup> for certain pharmaceuticals manufactured by Organon (specifically, Remeron tablet and Remeron SolTab) through direct agreements with Organon or group purchasing organization agreements with Organon. Unless otherwise stated, my opinions relate to the time period from September 13, 2001 to December 31, 2005 that is at issue in this lawsuit (the “Relevant Time Period”)<sup>2</sup> and the allegations that were addressed by the discovery therein.

2. Relators allege that Omnicare and the Acquired Pharmacies knowingly and intentionally violated the federal Anti-Kickback Statute (“AKS”), 42 U.S.C. § 1320a-7b(b), both by: (i) soliciting and receiving allegedly unlawful Discounts and Rebates from Organon through their purchase of Remeron tablet and Remeron SolTab pursuant to (a) contractual arrangements between Organon and Omnicare (the “Omnicare Direct Purchase Agreements”) and (b) purported contractual

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<sup>1</sup> The Acquired Pharmacies are American Pharmaceutical Services, Inc. (“APS”), NeighborCare, Inc. (“NeighborCare”), SunScript Pharmacy Corporation (“SunScript”), and NCS HealthCare, Inc. (“NCS”).

<sup>2</sup> Counsel has advised me that the relevant time frame for my analysis of the Discounts and Rebates, which is discussed in Section V. below, begins on September 13, 2001 based on the applicable statute of limitations. Although the Complaint alleges conduct from January 1, 1999 to December 31, 2005 (the “Alleged Relevant Time Period”), I do not address issues barred by the applicable statute of limitations. As such, I have not applied the pre-November 19, 1999 SDE/RDSH to the Discounts and Rebates in my analysis in Sections V. I reserve the right to supplement my report if the Court determines that the relevant time period for these purposes begins earlier than September 13, 2001.

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arrangements between Organon and certain Acquired Pharmacies (the “Acquired Pharmacies Purported Direct Purchase Agreements”); and (ii) receiving allegedly unlawful Discounts and Rebates from Organon through their purchase of Remeron tablet and Remeron SolTab pursuant to contractual arrangements between Organon and certain group purchasing organizations (the “GPO Agreements”), and thereby submitted false claims in violation of the civil False Claims Act (“FCA”), 31 U.S.C. § 3729.

**II. SUMMARY OF OPINIONS REQUESTED AND OPINIONS PROVIDED**

3. I have been asked to provide my opinion with respect to each of the following questions:

- a. Whether the Discounts and Rebates were common, usual and customary in the pharmaceutical industry during the Alleged Relevant Time Period.
  - b. What questions would be addressed and what materials were available and would have been considered during the Relevant Time Period in determining whether or not the Discounts and Rebates violated the AKS?
  - c. Whether companies in the health care industry, experienced health care attorneys, and regulators would have reasonably believed that the Discounts and Rebates contained in the Omnicare Direct Purchase Agreements and the GPO Agreements complied with, and were protected by, the statutory discount exception, 42 U.S.C § 1320a-7b(b)(3)(A) (the “Statutory Discount Exception” or the “SDE”).
  - d. Whether companies in the health care industry, experienced health care attorneys, and regulators would have reasonably believed that the Discounts and Rebates contained in the Omnicare Direct Purchase Agreements and the GPO Agreements complied with, and were protected by, the 1999 regulatory safe harbor for discounts, 42 C.F.R. § 1001.952(h) (the “Regulatory Discount Safe Harbor” or the “RDSH”).
  - e. Whether companies in the health care industry, experienced health care attorneys, and regulators reasonably would have believed that the Discounts and Rebates contained in the Omnicare Direct Purchase Agreements and the GPO Agreements did not violate the AKS.
4. For the reasons discussed in my report, my opinions are as follows:
- a. The Discounts and Rebates were common, usual and customary in the industry during the Alleged Relevant Time Period.

- b. During the Relevant Time Period, in determining whether or not the Discounts and Rebates violated the AKS, the following questions would have been addressed: (i) whether the Discounts and Rebates qualified for the SDE; (ii) whether the Discounts and Rebates qualified for the RDSH; and (iii) if the Discounts and Rebates did not qualify for either the SDE or the RDSH, whether the Discounts and Rebates had other characteristics that significantly increased the risk of fraud and abuse compared to safe harbored discounts. In addressing these questions during the Relevant Time Period, the following materials were available and would have been considered: (a) the statutory text and the legislative history of the SDE and the regulatory text, preamble and rulemaking history of the RDSH; (b) the available case law; (c) other relevant OIG guidance, including advisory opinions; and (d) the usual and customary discount and rebate practices in the industry.
- c. For the reasons discussed in my report, it is my opinion that companies in the health care industry, experienced health care attorneys and regulators would have reasonably believed that the Discounts and Rebates contained in the Omnicare Direct Purchase Agreements and the GPO Agreements complied with, and were protected by, the SDE since as early as November 19, 1999, when the OIG most recently interpreted the relevant statutory language.
- d. For the reasons discussed in my report, it is my opinion that companies in the health care industry, experienced health care attorneys and regulators would have reasonably believed that the Discounts and Rebates contained in the Omnicare Direct Purchase Agreements and the GPO Agreements complied with, and were protected by, the 1999 RDSH, which was effective November 19, 1999.
- e. For the reasons discussed in my report, it is my opinion that companies in the health care industry, experienced health care

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attorneys and regulators reasonably would have believed that the Discounts and Rebates contained in the Omnicare Direct Purchase Agreements and the GPO Agreements did not violate the AKS during the Relevant Time Period.

### **III. BACKGROUND AND QUALIFICATIONS**

5. I specialize in federal health care fraud and abuse laws and have over 35 years of experience in health care law, including substantial experience working in the federal government on the regulatory framework upon which I am opining. I am very familiar with the application of the AKS, the SDE and the RDSH to discount and rebate arrangements in the health care industry, including arrangements between pharmaceutical manufacturers and their customers.

6. From 1997 until 2003, I was the Chief of the Industry Guidance Branch of the Office of Counsel to the Inspector General of the United States Department of Health and Human Services (“HHS”), which is the federal agency responsible for, among other things, providing oversight of the Medicare program and of the federal portion of the Medicaid program. In that position, I was responsible for issuing formal guidance on behalf of HHS to the regulated community through advisory opinions, fraud alerts and special bulletins, compliance program guidance, and drafting regulations related to the fraud and abuse statutes and regulations enforced by the Office of Inspector General (“OIG”), including the AKS, 42 U.S.C. § 1320a-7(b), and the physician self-referral law, 42 U.S.C. § 1395nn (commonly known as the “Stark law”). My duties at OIG also included regularly providing informal oral guidance on behalf of HHS in response to inquiries from the public and other government agencies regarding the application of the AKS to various arrangements, including various discount and rebate arrangements. I also provided informal oral guidance on behalf of HHS in response to inquiries from the public and other government agencies regarding the application of the SDE and the RDSH to various discount and rebate arrangements. In addition, I worked closely with the United States Department of Justice (“DOJ”) in developing cases involving claims alleging violations of the AKS and Stark law, including the use of such claims as predicates for FCA litigation.

7. At the OIG, I was a principal author of the 1999 AKS “safe harbor” rulemaking, Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. 63518 (Nov. 19, 1999) (to be codified at 42 C.F.R. pt.

1001), which revised the RDSH to modify the reporting requirements and to permit greater flexibility for discounts and rebates on multiple products. I was also the principal author of several OIG advisory opinions, compliance program guidance, and informal “guidance” letters that addressed the application of the AKS, the SDE and the RDSH to discount and rebate arrangements, including Advisory Opinion 98-02 addressing the AKS and the SDE and/or the RDSH and the section of the Pharmaceutical Manufacturers Compliance Program Guidance on specific risk areas, 68 Fed. Reg. 23731, 23733-39 (May 5, 2003). I also was the principal author of the Stark Phase I and Phase II rulemakings, 66 Fed. Reg. 856 (Jan. 4, 2001) (to be codified at 42 C.F.R. pts. 441, 424); 69 Fed. Reg. 16054 (Mar. 26, 2004) (to be codified at 42 C.F.R. pts. 441, 424). As part of my duties as Chief of the OIG Industry Guidance Branch, I regularly spoke with health care attorneys, health care companies, federal and state regulators, and the DOJ regarding the federal AKS, the SDE, and the RDSH, including the application of each to various transactions, including discount and rebate arrangements.

8. From 1983 to 1996, prior to joining the OIG, I practiced health and regulatory law in the Dewey Ballantine law firm for 13 years, including 10 years as a partner, where among other activities, I advised health care clients, including pharmaceutical clients, regarding compliance with the AKS, the SDE and the RDSH.

9. I also served from 1981 to 1983 as Assistant Counsel to New York Governor Hugh Carey with principal responsibility for legislation and litigation affecting the health and human services agencies, including the Medicaid program, and from 1980 to 1981 as the Director of Legal Affairs for the New York Hospital.

10. Since May 2003, I have specialized my practice on the regulation of Medicare and Medicaid fraud and abuse. I have been retained by the federal government’s Centers for Medicare and Medicaid Services (“CMS”); the Office of the Assistant Secretary for Planning and Development in HHS; and the Medicare Payment Advisory Commission, an independent Congressional agency, to provide my expertise in federal health care fraud law and regulation. I regularly counsel health care entities, including pharmaceutical companies and their customers, on the Stark law, the AKS, the SDE and the RDSH and related regulations, including how to

ensure that such arrangements comply with those laws and regulations. I have also spoken on numerous occasions at industry conferences regarding the application of the AKS to discount and rebate arrangements and how to ensure that such arrangements comply with the SDE and the RDSH.

11. I was the co-chair of the American Health Lawyers Association Annual Program on Health Care Fraud and Compliance in 2013 and 2014 and on the Program Committee for its predecessor program, the American Health Lawyers Association/Health Care Compliance Association Fraud and Compliance Forum, from 2008 until 2012, the last two years of which I was co-chair. I am a member of the Advisory Board for the Bureau of National Affairs' Health Care Fraud Reporter. I was an adjunct professor at the University of Maryland Law School from 2001 to 2013. I am a past member of the Board of Directors of the American Health Lawyers Association. A copy of my current curriculum vitae is attached as Exhibit 1 to this report.

12. During the course of my career, I have reviewed dozens of purchasing agreements between (i) pharmaceutical manufacturers and (ii) purchasers of pharmaceuticals and/or representatives of such purchasers, such as group purchasing organizations, discussed more fully below.

13. I have been qualified at trial as an expert on the reasonableness of interpretation of the AKS. The matters in which I have given deposition or trial testimony as an expert witness in the last four years are set forth in Exhibit 2 to this report.

14. I am being compensated for my time at a rate of \$500 per hour for my services in preparing this report.

15. In addition to the material specifically cited herein, I have reviewed certain documents and deposition transcripts that counsel for Omnicare provided me, as specifically set forth in Exhibit 3 to this report. I have not undertaken any independent investigation. I have also reviewed the relevant statutes, regulations, preambles, and government guidance related to the AKS, the SDE and the RDSH. This report is based on my experience and knowledge of the custom and practice of regulators, the experienced health care bar, and the health care industry with

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respect to compliance with the federal AKS, the SDE and the RDSH, as well as my knowledge of the federal agency issued guidance, including OIG advisory opinions, other OIG-issued guidance, and the statutory, regulatory and case law to date.

16. I reserve the right to modify or amend my report based on further discovery in the litigation.

#### IV. BACKGROUND FACTS

##### A. DISCOUNTS AND REBATES IN THE PHARMACEUTICAL INDUSTRY AND THE GOVERNING STATUTORY AND REGULATORY FRAMEWORK

17. During the Relevant Time Period, manufacturers have offered a variety of reductions in prices on drugs to various purchasers. Price reductions given at the time of sale were and still are typically referred to as “discounts,” while price reductions given after the time of sale were and still are typically referred to as “rebates.” For example, a price reduction that is given to a consumer at the checkout counter is an example of a discount while a price reduction that is given after the consumer pays for the product, such as in the form of a check mailed by the manufacturer to the consumer after the consumer sends in a proof of purchase to the manufacturer, is an example of a rebate. Discounts and rebates were, and continue to be, very common in the pharmaceutical industry and are provided to various types of pharmaceutical purchasers, including institutional pharmacies.

18. During the Relevant Time Period, the pharmaceutical industry’s pricing practices were and continue to be governed by a complex regulatory and statutory framework, including the Social Security Act; the AKS, including the SDE; and the RDSH.

##### (i) Title XVIII of the Social Security Act – Medicare Part A (Cost-Based Insurance) and Part B (Charge-Based Insurance)

19. From its inception in 1965, Medicare consisted of two different insurance programs: Part A insured beneficiaries for hospital services and Part B insured beneficiaries for physician and non-hospital services. Medicare Part A was modeled on the Blue Cross hospital insurance plans developed and organized during the Great Depression by the hospitals themselves. Blue Cross only covered hospital services, together with some hospital-based physicians (*e.g.*, pathologists, radiologists and anesthesiologists) and made payments directly to the hospitals, which were primarily non-profits, based on their actual costs to provide the services. Importantly, hospitals received different reimbursement for the same services based on their individual cost structure. Similarly, Medicare Part A

originally paid hospitals directly based on Medicare's share of a hospital's actual and reasonable costs. Like Blue Cross, Medicare paid each hospital different amounts of reimbursement depending upon their individual costs and their mix of patients (*e.g.*, Medicare, commercial, self-pay).<sup>3</sup>

20. The Medicare Part B program, however, was modeled on the very different Blue Shield insurance programs. Blue Shield insurance was developed by physicians and designed to limit insurance company influence over the physician-patient relationship, including pricing. Medicare Part B adopted the Blue Shield model in part because the American Medical Association was opposed to any program pursuant to which the federal government would directly set physician payment rates or directly pay physicians.<sup>4</sup>

21. Blue Shield was structured as an indemnity insurance contract directly between the insurer (Blue Shield) and the insured patient. There was no contractual relationship between the insurer and the physician or other health care supplier.<sup>5</sup> Blue Shield's payment obligation was to reimburse the patient. The insurance contract required the insurer to reimburse the patient for a percentage of the non-hospital medical expenses actually incurred by the patient and paid by the patient, subject to a cap based on the usual and customary charges of physicians or suppliers in the area. The costs incurred by the physician or supplier to produce the service or provide the drug were irrelevant because reimbursement was based not on the supplier's actual cost but on the actual price charged to the patient.

22. Medicare Part B was virtually identical to Blue Shield. The basic indemnity benefits of Medicare Part B are described in SSA § 1833, 42 U.S.C. § 1395(l). With respect to pharmaceutical drugs, Medicare's obligation is:

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<sup>3</sup> See PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE 290-334, 385 (1982).

<sup>4</sup> *Id.*

<sup>5</sup> *Id.*

[T]here shall be paid from the Federal Supplementary Medical Insurance Trust Fund, in the case of each individual who is covered under the insurance program established by this part and incurs expenses for services with respect to which benefits are payable under this part, amounts equal to:

\* \* \*

(S) with respect to drugs and biologicals . . . not paid on a cost or prospective payment basis . . . , the amounts paid shall be 80 percent of the lesser of the actual charge or the payment amount established [elsewhere in the SSA].

*Id.* (emphasis added). Simply stated, Medicare Part B as an indemnity insurance plan, will reimburse the enrollee (*i.e.*, “the individual who is covered under [Medicare]”) for 80% of the enrollee’s incurred expenses for drugs or biologicals based on the supplier’s actual charges subject to a cap. Medicare Part B payment is not based on the supplier’s actual costs but only on the supplier’s actual charge to the enrollee.

23. These historical and significant differences between Part A cost-based reimbursement and Part B charge-based reimbursement are reflected throughout the Medicare statute and regulations. For example, Medicare Part A is an automatic entitlement program, requires no premium from enrollees, and requires minimal copayments. In contrast, Medicare Part B is optional, requires enrollees to pay substantial premiums, and requires enrollees to pay 20% copayments for most services. Medicare Part A originally reimbursed hospitals directly based on their individual actual and reasonable costs, while Medicare Part B originally reimbursed enrollees based on the usual and customary charges of their area physicians or suppliers for services the enrollees actually received. Medicare Part A providers can be excluded from the program if they claim “substantially in excess” of their usual costs; Medicare Part B suppliers may be excluded if they charge Medicare enrollees “substantially in excess” of their usual charge to other patients. SSA § 1128(b)(6), 42 U.S.C. § 1320a-7(b)(6). Medicare Part A hospitals are required to be prudent purchasers because they are reimbursed on their costs; Medicare Part B has no comparable requirement for Part B suppliers because their costs are irrelevant. *See, e.g.*, *OIG Anti-Kickback Provisions*, 56 Fed. Reg. 35952, 35979 (July 29, 1991) (to be codified at 42 C.F.R. pt. 1001), (stating, in comments to the 1991

RDSH rulemaking, that “we believe that this revision is consistent with [the Health Care Financing Administration’s (“HCFA”)] prudent buyer rules, which are not applicable to charge-based health care providers.”).

24. While the Medicare Part B program has evolved over time, it continues to be structured as an indemnity program that reimburses enrollees for actual charges enrollees have incurred for non-inpatient services (subject to a cap) and not on the physicians’ or suppliers’ costs to produce the services. While the cap has changed, the basic payment obligation has not. The original cap based on usual and customary charge in the community now typically takes the form of a fee schedule of some kind. *See, e.g.*, 42 C.F.R. 414 (1990) (payment under physician fee schedule); 42 C.F.R. 416 (1991) (payment under ambulatory surgery center fee schedule). However, the payment obligation is still the “lesser of” the supplier’s actual charge or the applicable cap.

25. The Medicaid program provides federal funds to states that implement medical insurance programs for certain categories of persons, primarily low income and disabled persons. State plans must meet standards set by federal regulation to qualify for the federal funds. Most state Medicaid programs are modeled on Medicare with cost-based separate prospective global payment mechanisms for hospital and other institutional providers (like Medicare Part A) and charge-based fee for service payments for physician services and other suppliers (*e.g.*, pharmacies) (like Medicare Part B).

(ii) The Anti-Kickback Statute

26. The AKS was enacted substantially in its current form in 1977. At all times, the AKS has applied equally to both Medicare and Medicaid. The AKS broadly prohibits persons from “solicit[ing] or receiv[ing] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind . . . in return for purchasing . . . any good, facility, service, or item for which payment may be made in whole or in part under this title.” Medicare-Medicaid Anti-Fraud and Abuse Amendments, Pub. L. No. 95-142, 91 Stat. 1175 (1977).

27. The 1977 AKS did not contain a specific scienter element. The prohibition applied if any person offered or paid, solicited or received any remuneration to

induce the purchase of an item or service reimbursable by Medicaid or Medicare. In 1980, the AKS was amended to require that violations must be “knowing and willful.” Omnibus Reconciliation Act of 1980, Pub. L. No. 96-499, 94 Stat. 2599 (1980).

28. “Remuneration” was broadly defined as “(including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind.” In the 1991 AKS Safe Harbor Final Rulemaking, the OIG interpreted the term to mean the transfer of anything of value “in any form or manner whatsoever” to a party in a position to refer Medicare, Medicaid or other federal health care program patients or business that is reimbursable by Medicare, Medicaid or other federal health care programs. OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952, 35958 (July 29, 1991) (to be codified at 42 C.F.R. pt. 1001).

(iii) The Statutory Discount Exception to the Anti-Kickback Statute

29. The 1977 AKS contained two statutory exceptions to protect certain transfers of value that would not constitute “remuneration” prohibited by the AKS. One of those statutory exceptions, the Statutory Discount Exception, is of particular relevance here as it protected discounts and other reductions in price.<sup>6</sup>

30. The Statutory Discount Exception as enacted provided that the AKS did not apply to:

a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program.

42 U.S.C § 1320a-7b(3)(A).

(iv) The Regulatory Discount Safe Harbor

31. In 1987, HHS was given authority to create additional exceptions to the AKS by the Medicare and Medicaid Patient and Program Protection Act of 1987. *See* Pub. L. No. 100-93, § 14(a), 101 Stat. 680, 697 (1987). HHS delegated this authority to the OIG, and, using this authority, the OIG proposed in 1989, and promulgated in

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<sup>6</sup> The other original statutory exception was for compensation to employees. 42 U.S.C. § 1320a-7b(b)(3)(B).

1991, the RDSH, identifying a number of price reduction practices that are immunized from prosecution under the AKS. Although compliance with the RDSH is not required, the OIG made clear in promulgating the RDSH that “we have attempted to provide bright lines, to the extent possible, for safe harbors in order to provide clarity and predictability as to what conduct is immune from government action.” OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952, 35954 (July 29, 1991) (to be codified at 42 C.F.R. pt. 1001); *see also* OFFICE OF INSPECTOR GEN., OIG FACT SHEET: FEDERAL ANTI-KICKBACK LAW AND REGULATORY SAFE HARBORS (Nov. 1999) (“Safe harbors immunize certain payment and business practices that are implicated by the anti-kickback statute from criminal and civil prosecution under the statute.”).

32. The RDSH was modified in November 1999. Accordingly, the 1999 RDSH was in effect for the entire Relevant Time Period. As stated above, I was a principal author of the 1999 modification of the RDSH.

33. The regulatory safe harbors to the AKS define arrangements that might implicate the AKS, but that the Secretary of HHS determined warrant protection. If an arrangement qualifies for a safe harbor, it is protected or “immunized” from prosecution under the AKS. *See, e.g.*, OFFICE OF INSPECTOR GEN., OIG FACT SHEET: FEDERAL ANTI-KICKBACK LAW AND REGULATORY SAFE HARBORS (Nov. 1999). Strict compliance with all elements of a safe harbor is required in order to qualify for its protections; however, a failure to strictly comply with all elements of a safe harbor does not mean that the arrangement at issue violates the AKS.

34. The 1999 RDSH, 42 C.F.R. § 1001.952(h) (1999), defines what qualifies as a discount and sets out a party’s obligations in order to qualify for the RDSH. A party’s obligations vary depending on: (i) whether the party is the seller, the buyer, or an offeror (someone offering a discount other than the seller); and (ii) on how the buyer is reimbursed by the Medicare or Medicaid program. A buyer or seller qualifies for the RDSH so long as it satisfies the conditions applicable to its status, regardless of any other parties’ actions. 42 C.F.R. § 1001.952(h) (1999) (“‘[R]emuneration’ does not include a discount . . . from a seller as long as the buyer

complies with the applicable standards of paragraph (h)(1) of this section and the seller complies with the applicable standards of paragraph (h)(2) of this section.”).

35. The provisions of the 1999 RDSH relevant to Omnicare’s and the Acquired Pharmacies’ purchases from Organon provide:

(h) Discounts. As used in section 1128B of the Act, “remuneration” does not include a discount, as defined in paragraph (h)(5) of this section, on an item or service for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs for a buyer as long as the buyer complies with the applicable standards of paragraph (h)(1) of this section . . . .

(1) With respect to the following three categories of buyers, the buyer must comply with all of the applicable standards within one of the three following categories—

\* \* \*

(iii) If the buyer is an individual or entity in whose name a claim or request for payment is submitted for the discounted item or service and payment may be made, in whole or in part, under Medicare, Medicaid or other Federal health care programs (not including individuals or entities defined as buyers in (i)[health maintenance organizations and competitive health plans with Medicare or Medicaid contracts] or (ii) [entities that file cost reports with CMS or a state Medicaid program]), the buyer must comply with both of the following standards—

(A) The discount must be made at the time of the sale of the good or service or the terms of the rebate must be fixed and disclosed in writing to the buyer at the time of the initial sale of the good or service; and

(B) the buyer (if submitting the claim) must provide, upon request by the Secretary or a State agency, information [specified in the regulation regarding the purchase price] provided by the seller . . . .

\* \* \*

(4) For purposes of this paragraph, a rebate is any discount the terms of which are fixed and disclosed in writing to the buyer at the time of the initial purchase to which the discount applies, but which is not given at the time of sale.

(5) For purposes of this paragraph, the term discount means a reduction in the amount a buyer (who buys either directly or through a wholesaler or a group

purchasing organization) is charged for an item or service based on an arms-length transaction. The term discount does not include—

- (i) Cash payment or cash equivalents (except that rebates as defined in paragraph (h)(4) of this section may be in the form of a check);
- (ii) Supplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service, unless the goods and services are reimbursed by the same Federal health care program using the same methodology and the reduced charge is fully disclosed to the Federal health care program and accurately reflected where appropriate, and as appropriate, to the reimbursement methodology;
- (iii) A reduction in price applicable to one payer but not to Medicare, Medicaid or other Federal health care programs;
- (iv) A routine reduction or waiver of any coinsurance or deductible amount owed by a program beneficiary;
- (v) Warranties;
- (vi) Services provided in accordance with a personal or management services contract; or
- (vii) Other remuneration, in cash or in kind, not explicitly described in paragraph (h)(5) of this section.

42 C.F.R. § 1001.952(h) (1999) (emphasis added).

36. Throughout the Relevant Time Period, Omnicare was a buyer described in 42 C.F.R. § 1001.952(h)(1)(iii) (1999). Omnicare was neither a managed care entity contracting with Medicare or Medicaid nor did Omnicare file cost reports with CMS or any State Medicaid agency. Rather, pharmacies like Omnicare and the Acquired Pharmacies were generally categorized as “charge-based” suppliers during the Relevant Time Period. This means that Medicaid would pay no more than the supplier’s “usual and customary charge to the public.” Over the years, government programs have instituted fee schedules or similar limits on charge-based services, so that Medicare and Medicaid pay the lesser of a fee schedule (or other limit) or the supplier’s usual and customary charge. For example Medicaid reimbursed suppliers the lesser of: (i) estimated acquisition costs plus reasonable dispensing

fees established by the agency; or (ii) the supplier's usual and customary charges to the general public. *See* 42 CFR § 447.331(b)(1)-(2) (1987). This payment structure is considered charge-based reimbursement, since payment is not based on the supplier's actual incurred costs and is ultimately limited by its usual charge.

37. The RDSH changed considerably from the time it was first proposed in 1989. The 1989 proposed safe harbor would have required charge-based suppliers like Omnicare and the Acquired Pharmacies to actually reduce their charges to Medicaid or Medicare by the amount of any discount they received for items or services that were used in providing the Medicaid or Medicare service. Fraud and Abuse OIG Anti-Kickback Provisions, 54 Fed. Reg. 3088, 3093 (proposed Jan. 23, 1989) (to be codified at 42 C.F.R. pt. 1001). However, the 1991 Final Rule eliminated the requirement that charge-based suppliers reduce their charges to reflect any discounts they had received. *See* OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952, 35979-80 (July 29, 1991) (to be codified at 42 C.F.R. pt. 1001). The 1991 Final Rule required the supplier to report any discount received for any service or item that was separately claimed. *Id.* That requirement was eliminated in the 1999 RDSH. Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. 63518, 63529 (Nov. 19, 1999) (to be codified at 42 C.F.R. pt. 1001). In addition, the 1991 Final Rule did not protect rebates given to charge-based suppliers, but the 1999 RDSH extended protection to rebates given to charge-based suppliers. *Id.*

#### B. COMMON TYPES OF DISCOUNTS AND REBATES

38. From 1977 when the SDE was enacted through the Relevant Time Period, pharmaceutical manufacturers have offered a variety of discounts and rebates to various purchasers, including institutional pharmacies like Omnicare and the Acquired Pharmacies, to incentivize the purchase of their products. Discounts, including rebates, are commonly used to incentivize buyers to purchase a manufacturer's pharmaceuticals. With respect to institutional pharmacies, such discounts and rebates took various forms, including discounts provided at the time

of purchase (“Point of Purchase Discounts”), volume rebates, market share rebates, and discounts for preferred placement and formulary compliance activities.

- Point of Purchase Discounts. A Point of Purchase Discount is a reduction in the price of a drug usually expressed as a percentage off of a benchmark price (usually the wholesale acquisition cost (“WAC”) of the drug for brand name drugs). Point of Purchase discounts include “ramp up” discounts, which are provided to a customer for a given period of time, after which the discount could switch to another form of price reduction, such as a price reduction given after the sale is made based on market share (discussed below).
- Volume Rebates. A volume rebate is a specified reduction in the price of a drug which is given after the sale of the drug and is usually expressed as a percentage rebate based on the amount of the drug purchased during a specified period (*e.g.*, a quarter). Usually, the higher the volume of qualifying purchases, the greater the rebate.
- Market Share Rebates. A market share rebate is a specified reduction in the price of a drug which is given after the sale of the drug and is usually expressed as a percentage rebate based on the customer’s purchases of the drug as compared to a class of drugs sold for the same indication and identified in the purchase contract. A variation of the market share rebate is a specified reduction in the price of a drug that is given after the sale of the drug and is usually expressed as a percentage rebate based on the customer’s utilization of the drug as compared to a “benchmark” number.
- Preferred Placement and Formulary Compliance Discounts. A formulary generally is a list of prescription drugs or pharmaceutical products covered by a health plan.<sup>7</sup> A discount for preferred placement is a specified reduction

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<sup>7</sup> The Geriatric Pharmaceutical Care Guidelines is not a traditional formulary. It is a clinically based reference tool for drug product comparison specifically focused on the geriatric population. It does not restrict the ability of a physician to prescribe any drug or identify which drugs are covered by a health plan. *See, e.g.*, OMNI-BT0000261059-1129 at OMNI-BT0000261084, OMNI-BT0000261087.

in the price of a drug offered by the manufacturer if the purchaser designates the manufacturer's drug as a preferred drug on the purchaser's formulary. A formulary compliance discount is a specified reduction in the price of a drug offered by the manufacturer if the purchaser takes some steps to promote compliance with the formulary, such as a therapeutic interchange or similar program. A therapeutic interchange program refers to a clinical initiative by a pharmacy to replace a non-preferred drug on a formulary with the preferred drug on a formulary in the same therapeutic class, providing it is approved by the pharmacy's pharmacy and therapeutics or similar committee to be therapeutically equivalent and the conversion otherwise complies with the relevant regulations. These discounts could be given either at the time of purchase or after the purchase as a rebate.

C. THE OMNICARE DIRECT PURCHASE AGREEMENTS WITH ORGANON

39. One of the means by which Omnicare, a charge-based supplier, purchased Remeron tablet and Remeron SolTab from Organon was through direct purchase agreements. I have reviewed those direct purchase agreements and the associated amendments. Specifically, I have reviewed the following, which are collectively referred to as the "Omnicare Direct Purchase Agreements" (as noted above):

- The unsigned October 2001 Purchase Agreement between Organon and Omnicare (effective date of Oct. 1, 2001), Bates numbered BA-JBET-000969-982 (the "2001 Direct Purchase Agreement");
- The February 2002 Purchase Agreement between Organon and Omnicare (effective date of Mar. 1, 2002), Bates numbered BA-JBET-000995-1009 (the "2002 Direct Purchase Agreement"); and
- The amendments to the 2002 Direct Purchase Agreement, dated July 2002 (BA-JBET-001010-1012), October 2002 (BA-JBET-001013), March 2003 (BA-JBET-001017), April 2003 (BA-JBET-001018), October 2003 (BA-JBET-001024-1026), January 2004 (BA-JBET-001027-1028) and April 2004 (BA-JBET-001029-1030).

(i) The 2001 Direct Purchase Agreement

40. The 2001 Direct Purchase Agreement included discounts and rebates, the terms of which were fixed and set forth in writing in the agreement, including the manner in which the amounts of those discounts and rebates would be calculated.

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED] See

BA-JBET-000969-982 at BA-JBET-000979-982.

41. [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED] See *id.* at BA-JBET-000971.

42. The 2001 Direct Purchase Agreement did not condition any discount or rebate on Omnicare implementing any Remeron tablet or Remeron SolTab initiatives.

43. The 2001 Direct Purchase Agreement did not condition any discount or rebate on Omnicare placing Remeron tablet or Remeron SolTab on a formulary or designating them as preferred drugs.<sup>8</sup>

44. [REDACTED]  
[REDACTED] See  
*id.* at BA-JBET-000972.

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<sup>8</sup> Indeed, as noted in footnote 7 above, Omnicare did not have a traditional formulary.

45. As outlined above, the terms of the discounts and rebates in the 2001 Direct Purchase Agreement were fixed and set out in writing in the agreement itself at the time of the initial sale qualifying for the discounts and rebates. *See id.* at BA-JBET-000978-982; Sept. 28, 2001 Omnicare Purchasing Memorandum, OMNI-BT00115389-90.

(ii) The 2002 Direct Purchase Agreement

46. The 2002 Direct Purchase Agreement included discounts and rebates, the terms of which were fixed and set forth in writing in the agreement, including the manner in which the discounts and rebates would be calculated. [REDACTED]

[REDACTED]

[REDACTED] *See* BA-JBET-000995-1009 at BA-JBET-001004-1007.

47. [REDACTED]

48. As with the 2001 Direct Purchase Agreement, the 2002 Direct Purchase Agreement, including the amendments thereto (discussed below), did not condition any discount or rebate on Omnicare implementing any Remeron tablet or Remeron SolTab initiatives.

49. As with the 2001 Direct Purchase Agreement, the 2002 Direct Purchase Agreement, including the amendments thereto (discussed below), did not condition any discount or rebate on Omnicare placing Remeron tablet or Remeron SolTab on a formulary or designating them as preferred drugs.

50. [REDACTED]

51. As with the 2001 Direct Purchase Agreement, and as outlined above, the terms of the discounts and rebates in the 2002 Direct Purchase Agreement were fixed and set out in writing in the agreement itself at the time of the initial sale qualifying for the discounts and rebates. *See id.* at BA-JBET-001004-1007; Feb. 7, 2002 Omnicare Purchasing Memorandum, OMNI-BT00115392; *see also* OMNI-BT-1123304.

52. The terms of the discounts and rebates set forth in the amendments to the 2002 Direct Purchase Agreement were also fixed and set out in writing in the amendments, and included the following: the July 2002 amendment (BA-JBET-001010-1012) [REDACTED]

[REDACTED] the October 2002 amendment (BA-JBET-001013) [REDACTED]  
[REDACTED]; the March 2003 amendment (BA-JBET-001017) [REDACTED]  
[REDACTED]; the April 2003 amendment (BA-JBET-001018)  
( [REDACTED]  
[REDACTED]; the October 2003 amendment (BA-JBET-001024-1026) [REDACTED]  
[REDACTED] the January  
2004 amendment (BA-JBET-001027-1028) [REDACTED]  
[REDACTED]; and  
the April 2004 amendment (BA-JBET-001029-1030) [REDACTED]  
[REDACTED]  
[REDACTED]

#### D. THE GPO AGREEMENTS WITH ORGANON

53. In addition to directly contracting with pharmaceutical manufacturers, pharmacies can purchase pharmaceuticals through Group Purchasing Organizations (“GPOs”). GPOs negotiate and contract with pharmaceutical manufacturers and make the discounts and rebates that are included in their

negotiated contracts with the manufacturers available to their members. GPOs' members include both institutional and independent pharmacies throughout the country.<sup>9</sup> The greater the purchasing power of its members, the larger the discounts the GPO should be able to negotiate. Accordingly, GPOs seek to attract as many members as they can.

54. At various points during the Relevant Time Period, Omnicare and the Acquired Pharmacies purchased Remeron tablet and Remeron SolTab through GPOs. I have reviewed the following contracts and amendments – some of which are unsigned – between Organon and each of the following GPOs: Managed Healthcare Associates, Inc. (“MHA”); GeriMed; Owen Healthcare, Inc. (“Owen”); Cardinal Health Provider Pharmacy Services (“Cardinal”); and Committed Provider Services (“CPS”) (collectively referred to as the “GPO Agreements,” as noted above). Each of the GPO Agreements described below allowed Omnicare and the Acquired Pharmacies to purchase Remeron tablet and/or Remeron SolTab under the terms of those GPO Agreements.<sup>10</sup> In addition, each would have been available to other institutional pharmacies throughout the country that were members of those GPOs.

(i) MHA:

- A February 1999 GPO Purchase Agreement between Organon and MHA (effective date of Feb. 17, 1999), Bates numbered BA-JBET-000494-503 (the “1999 MHA Contract”) and amendments to the 1999 MHA Contract, dated March 1999 (BA-JBET-000504-505) and April 1999 (BA-JBET-000506-507); and

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<sup>9</sup> GPOs are also covered by one of the regulatory safe harbors. See 42 C.F.R. § 1001.952(j) (1999). The GPO safe harbor allows GPOs to receive administrative fees from healthcare companies for “arranging for” the purchases of the companies’ products by the GPOs’ members.

<sup>10</sup> The GPO Agreements that I reviewed were produced by Relators. I am not aware of Omnicare or the Acquired Pharmacies having access to the actual GPO Agreements and have no knowledge of whether Omnicare or the Acquired Pharmacies actually saw the GPO Agreements or were aware of their terms or conditions.

- A February 2001 GPO Purchase Agreement between Organon and MHA (effective date of Mar. 1, 2001), Bates numbered BA-JBET-000515-530 (the “2001 MHA Contract”) and amendments to the 2001 MHA Contract, dated September 2001 (BA-JBET-000537) and October 2001 (BA-JBET-000535).
- As set forth in exhibits to these contracts, Omnicare was eligible to purchase under the 1999 MHA Contract and the 2001 MHA Contract prior to entering into the 2001 Direct Purchase Agreement;<sup>11</sup> APS, NeighborCare and NCS were also eligible to purchase under the 1999 MHA Contract; and SunScript was eligible to purchase under the 2001 MHA Contract.

(ii) GeriMed:

- A February 1999 GPO Purchase Agreement between Organon and GeriMed (effective date of Feb. 17, 1999), Bates numbered BA-JBET-000281-290 (the “1999 GeriMed Contract”); and
- A February 2001 GPO Purchase Agreement between Organon and GeriMed (effective date of Mar. 1, 2001), Bates numbered BA-JBET-000308-324 (the “2001 GeriMed Contract”).
- As set forth in exhibits to these contracts, Omnicare was eligible to purchase under the 1999 GeriMed Contract and the 2001 GeriMed Contract; NeighborCare and NCS were eligible to purchase under the 1999 GeriMed Contract; and SunScript was eligible to purchase under the 2001 GeriMed Contract.

(iii) CPS:

- An unsigned January 2001 GPO Purchase Agreement between Organon and CPS (effective date of Mar. 1, 2001), Bates numbered BA-JBET-000569-582 (the “CPS Contract”).

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<sup>11</sup> In October 2001, the 2001 MHA Contract was amended to exclude Omnicare from the agreement. See BA-JBET-000535.

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- As set forth in an exhibit to this unsigned contract, NCS may have been eligible to purchase under the CPS Contract.

(iv) Owen:

- A March 2001 GPO Purchase Agreement between Organon and Owen (effective date of Mar. 1, 2001), Bates numbered BA-JBET-000428-443 (the "Owen Contract").
- As set forth in an exhibit to this contract, NeighborCare and APS were eligible to purchase under the Owen Contract.

(v) Cardinal:

- A March 2002 GPO Purchase Agreement between Organon and Cardinal (effective date of Mar. 1, 2002), Bates numbered BA-JBET-000464-478 (the "Cardinal Contract") and an amendment to the Cardinal Contract, dated July 2002 (BA-JBET-000479-481).
- As set forth in an exhibit to this contract, NeighborCare was eligible to purchase under the Cardinal Contract.

55. By way of overview, the GPO Agreements offered various types of reductions in price for Remeron tablet and/or Remeron SolTab, including: [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

56. I have included below a chart specifying the relevant discount and rebate provisions in the GPO Agreements.

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Agreement	Discount/Rebate Provisions Included in the Contract	Bates No.
1999 MHA Contract; and 1999 GeriMed Contract	<p>These</p> <p>(i) [REDACTED]; and</p> <p>(ii) [REDACTED]</p>	<p>BA-JBET-000494-503 at BA-JBET-000500-502 (MHA);</p> <p>BA-JBET-000281-290 at BA-JBET-000287-289 (GeriMed).</p>
2002 Cardinal Contract	<p>This co</p> <p>(i) [REDACTED]</p> <p>(ii) [REDACTED]</p> <p>(iii) [REDACTED]</p>	<p>BA-JBET-000464-478 at BA-JBET-000474-477.</p>

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Agreement	Discount/Rebate Provisions Included in the Contract	Bates No.
2001 MHA Contract; 2001 GeriMed Contract; 2001 CPS Contract; and 2001 Owen Contract	<p>These contracts included:</p> <p>(i) [REDACTED]</p> <p>(ii) [REDACTED]</p> <p>(iii) [REDACTED]</p> <p>(iv) [REDACTED]</p>	<p>BA-JBET-000515-530 at BA-JBET-000525-530 (MHA);</p> <p>BA-JBET-000308-325 at BA-JBET-000318-323 (GeriMed);</p> <p>BA-JBET-000569-584 at BA-JBET-000579-584 (CPS);</p> <p>BA-JBET-000428-443 at BA-JBET-000437-443 (Owen).</p>

E. THE ACQUIRED PHARMACIES' PURPORTED DIRECT PURCHASE AGREEMENTS WITH ORGANON

57. I have reviewed the following documents that purport to be agreements between Organon and APS; Organon and NCS; and Organon and Neighborcare, most of which are either unsigned or only partially executed:

(i) APS:

- An unsigned March 2000 Purchase Agreement between Organon and APS (effective date of Mar. 1, 2000), Bates numbered ORG-TX08CID0000652-665 (the "APS Contract"), and an unsigned amendment to the APS Contract, dated February 2001 (ORG-TX08CID0000648-651).

(ii) NeighborCare:

- An unsigned March 2002 Purchase Agreement between Organon and NeighborCare (effective date of Mar. 1, 2002), Bates numbered ORG-BOS0149465-477 (the “NeighborCare Contract”).

(iii) NCS:

- A March 2002 Purchase Agreement between Organon and NCS (effective date of Mar. 1, 2002), Bates numbered ORG-BOS0085779-792 (the “NCS Contract”), and amendments to the NCS Contract, dated July 2002 (signed) (OMNI-BT00115410-413) and October 2002 (not fully executed) (OMNI-BT00115414).

58. By way of overview, these documents purport to offer various types of reductions in price for Remeron tablet and/or Remeron SolTab, including: [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] See ORG-

TX08CID0000652-65 at ORG-TX08CID0000653, ORG-TX08CID0000663; ORG-BOS0149465-77 at ORG-BOS0149467-68; ORG-BOS0085779-92 at ORG-BOS0085781-82.

**V. OPINIONS****A. WHETHER THE DISCOUNTS AND REBATES WERE COMMON, USUAL AND CUSTOMARY IN THE INDUSTRY**

59. Based on the facts set forth in Section IV. above and my experience, including as Chief of the Industry Guidance Branch of the Office of Counsel to the Inspector General of HHS during much of the Alleged Relevant Time Period, and having reviewed dozens of pharmaceutical purchasing agreements containing various types of price reductions, including discounts and rebates, over the course of my career, it is my opinion that all of the Discounts and Rebates offered pursuant to the Omnicare Direct Purchase Agreements were common, usual, and customary in the industry from at least the late 1970s through the Alleged Relevant Time Period.

60. Based on the facts set forth in Section IV. above and my experience, including as Chief of the Industry Guidance Branch of the Office of Counsel to the Inspector General of HHS during much of the Alleged Relevant Time Period, and having reviewed dozens of pharmaceutical purchasing agreements containing various types of price reductions, including discounts and rebates, over the course of my career, it is my opinion that all of the Discounts and Rebates offered pursuant to the GPO Agreements were common, usual, and customary in the industry from at least the late 1970s through the Alleged Relevant Time Period.

61. Based on the facts set forth in Section IV. above and my experience, including as Chief of the Industry Guidance Branch of the Office of Counsel to the Inspector General of HHS during much of the Alleged Relevant Time Period, and having reviewed dozens of pharmaceutical purchasing agreements containing various types of price reductions, including discounts and rebates, over the course of my career, it is my opinion that all of the Discounts and Rebates purportedly offered pursuant to the Acquired Pharmacies' Purported Direct Purchase Agreements were common, usual, and customary in the industry from at least the late 1970s through the Alleged Relevant Time Period.

62. Moreover, the fact that similar Discounts and Rebates are contained in the Omnicare Direct Purchase Agreements, the Acquired Pharmacies' Purported Direct

Purchase Agreements, the five different GPO Agreements discussed herein (each of which would have been available to other institutional pharmacies throughout the country that were members of those GPOs), and agreements between Organon and PharMerica (one of the nation's largest long-term care pharmacy providers during the Relevant Time Period)<sup>12</sup> further demonstrates that these types of Discounts and Rebates are usual and customary in the industry.

63. In addition, others in the industry have recognized that pharmaceutical manufacturers' practice of offering discounts and rebates to purchasers of their pharmaceuticals is common in the industry. *See generally* Health Strategies Consultancy LLC, "Follow The Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain," prepared for the Kaiser Family Foundation, Mar. 2005.

B. WHAT QUESTIONS WOULD BE ADDRESSED AND WHAT MATERIALS WERE AVAILABLE AND WOULD HAVE BEEN CONSIDERED DURING THE RELEVANT TIME PERIOD IN DETERMINING WHETHER OR NOT THE DISCOUNTS AND REBATES VIOLATED THE AKS?

64. Based on my experience, including as Chief of the Industry Guidance Branch of the Office of Counsel to the Inspector General of HHS during much of the Relevant Time Period, it is my opinion that during the Relevant Time Period, in determining whether or not the Discounts and Rebates violated the AKS, the following questions would have been addressed: (i) whether the Discounts and Rebates qualified for the SDE; (ii) whether the Discounts and Rebates qualified for the RDSH; and (iii) if the Discounts and Rebates did not qualify for either the SDE or the RDSH, whether the Discounts and Rebates had other characteristics that significantly increased the risk of fraud and abuse compared to safe harbored discounts and rebates.

65. In addressing the above-described questions during the Relevant Time Period, the following materials were available and would have been considered:

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<sup>12</sup> *See, e.g.*, March 2002 Long Term Care Purchase Agreement between PharMerica and Organon, BA-JBET-000934-46.

(a) the statutory text and legislative history of the SDE and the regulatory text, preamble and rulemaking history of the RDSH; (b) the available case law; (c) other relevant OIG guidance, including advisory opinions; and (d) the usual and customary discount and rebate practices in the industry. The information that would have been considered includes the information set forth below.

(i) The Statutory Discount Exception

66. As set forth above in Section IV.A.(iii), since 1977, when the SDE was enacted, and continuing through to the present, the SDE has provided that discounts and rebates are not unlawful remuneration prohibited by the AKS if the discount or rebate is “properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program.” 42 U.S.C § 1320a-7b(b)(3)(A) (2010).

67. Since the time the SDE was enacted through to the present, cost reporting entities have been required to accurately reflect their actual net costs on their cost reports to get reimbursement under Medicare and Medicaid, but charge-based suppliers such as Omnicare and the Acquired Pharmacies have never been required to submit cost reports.

68. In determining whether discounts and rebates such as those contained in the Omnicare Direct Purchase Agreements and the GPO Agreements at issue were “properly disclosed and appropriately reflected in the costs claimed or charges made” during the Relevant Time Period, the following materials were available and would have been considered: (a) the text of the AKS and SDE itself, the legislative history, and the relevant OIG rulemaking; and (b) the limited case law interpreting the SDE.

(a) The Statutory Text and Legislative History of the SDE and the Relevant OIG Rulemaking

69. As previously discussed, the SDE provides that the AKS does not apply to: a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is

properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program.

42 U.S.C § 1320a-7b(b)(3)(A) (2010).

70. The Senate Finance Committee explained the SDE as follows:

The bill would specifically exclude the practice of discounting or other reductions in price from the range of financial transactions to be considered illegal under medicare and medicaid, but only if such discounts are properly disclosed and reflected in the cost for which reimbursement could be claimed. The committee included this provision to ensure that the practice of discounting in the normal course of business transactions would not be deemed illegal. In fact, the committee would encourage providers to seek discounts as a good business practice which results in savings to medicare and medicaid program costs.

S. REP. NO. 95-453, at 12 (1977).

71. In promulgating its safe harbors in 1991 and 1999, including the Regulatory Discount Safe Harbor discussed more fully below, the OIG interpreted the SDE's phrase "properly disclosed and appropriately reflected in the costs claimed or charges made" to be specific to the Medicare and Medicaid reimbursement methodology applicable to the good or service at issue. In 1991, the OIG noted, "[w]e believe it is in the public interest to provide the health care community with our interpretation of the meaning of certain important statutory terms, for example, 'appropriately reflect' in the discount exception . . . ." OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952, 35957 (July 29, 1991) (to be codified at 42 C.F.R. pt. 1001).

72. The OIG further stated in 1991 "that it is appropriate to treat charge-based health care providers differently from cost-based health care providers for the purposes of requiring the discount to be passed along to the program. Such an approach is far preferable than a blind adherence to uniform treatment of health care providers. We believe that such a position is a reasonable reading of the [Statutory Discount Exception's] requirement that 'the reduction in price [be] . . . appropriately reflected in the costs claimed or charges made by the provider or entity.'" *Id.* at 35980. Accordingly, the OIG determined that the statutory language of the SDE did not require charge-based suppliers to reduce their Medicare or Medicaid charges to reflect any discounts or rebates the suppliers may have

received. *Id.* The OIG nevertheless determined that, while the supplier's charge did not have to be reduced, the discount would still have to be reported on the claim submitted to CMS if it was a separately reimbursable item in order to be "properly disclosed." *Id.*

73. Thereafter, in 1999, the OIG again interpreted the SDE's phrase "properly disclosed and appropriately reflected." The OIG reaffirmed that a discount was "appropriately reflected" in the claim made even though there was no reduction in the charge. More importantly, the OIG again addressed the "properly disclosed" requirement for charge-based suppliers and eliminated the requirement that the discount be disclosed on the claim form for separately reimbursable items. The OIG determined that the discount was "properly disclosed" so long as the supplier disclosed the discount or net price to the Secretary if requested, but that no affirmative action was required. Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. 63518, 63527 (Nov. 19, 1999) (to be codified at 42 C.F.R. pt. 1001) ("We are eliminating the requirement that charge-based buyers report discounts on claims submitted to the Federal programs; however, we are retaining the requirement that such buyers provide documentation of discounts to the Secretary upon request.").

(b) Available Case Law Addressing the SDE and the AKS

74. In addition to the statutory text of the SDE and the relevant OIG rulemaking history described above, any relevant case law interpreting the SDE would have been considered in determining whether the SDE protected discounts and rebates. During the Relevant Time Period, there was limited case law addressing the application of the SDE's disclosure requirement to charge-based buyers such as Omnicare and the Acquired Pharmacies. There were no reported cases that substantively interpreted the SDE prior to the OIG's 1999 rulemaking promulgating the 1999 RDSH, which applies here.

75. One case addressing the disclosure requirement in the SDE was *United States v. Shaw*, 106 F. Supp. 2d 103 (D. Mass. 2000), which addressed the SDE's

application to a seller and allegations that must be contained in an indictment charging a criminal violation of the AKS, and therefore was of little definitive guidance for buyers considering whether Discounts and Rebates such as those contained in the Omnicare Direct Purchase Agreements and GPO Agreements fell within the SDE.<sup>13</sup>

76. The *Shaw* case involved a motion to dismiss criminal charges involving a marketing arrangement that the government alleged was a violation of the AKS and that the defense argued was protected by the SDE. Shaw, an executive of NMC Medical Products, which sold dialysis supplies to providers, was alleged to have offered discounts on dialysis supplies to providers on condition that the providers referred their laboratory testing to another NMC subsidiary that provided clinical laboratory services. *Id.* at 106-07. The defense argued that the indictment should be dismissed because it failed to allege that the purported unlawful marketing arrangement was not protected by the SDE. *Id.* at 109.

77. As part of the court's analysis, it addressed the application of the language in the SDE that the discount had to be "properly disclosed and appropriately reflected" in the costs claimed and charges made and the scope of a seller's obligation to make such disclosure, given that sellers did not submit claims or charges to the government. The defendant argued that the discounts had been properly disclosed because its invoices accurately reflected the discounts. *Id.* at 118. The government argued that accurate disclosure of the amounts of the

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<sup>13</sup> Although another case, *U.S. ex rel. Walsh v. Eastman Kodak Co.*, 98 F. Supp. 2d 141 (D. Mass. 2000), refers to the SDE ("Relator's theory is that by failing to ensure that its discount program met the statutory discount exception to that statute, [the defendant] in turn violated the FCA."), it does not appear from the court's opinion that the SDE (or the RDSH) was invoked by the defendant as a defense and, in any event, the court did not substantively address the SDE (or the RDSH). Instead, the court concluded that (i) the defendant's disclosures in reports provided to hospitals negated any inference of improper scienter and (ii) "regardless of whether the discounts fell within the AKS's statutory discount exception, plaintiff never alleges with the requisite particularity that [the defendant] knowingly presented, caused the presentation of, or conspired to present any false cost report to the government." *Id.* at 149.

discount or the net price was not sufficient and that the exception required “full disclosure of the material terms of the transaction.” *Id.*

78. The court rejected the government’s contention that the “material” terms had to be disclosed:

The government’s suggested reading that the “material terms” of the transaction be disclosed is unpersuasive. It begs two questions: material to whom and in what context? The parties to the transaction might consider many more terms “material” than those needed by Medicare or Medicaid for reimbursement purposes. What the parties to the transaction may consider material, however, is not decisive as to whether the purpose of the statute is satisfied. The statute aims at reduction of the price of the goods or services through disclosure, so a lower price can be reflected in lower costs claimed from or charged to a federal health care program. In this way, the federal health program may benefit from a reduction in price offered and received. Whether disclosures are “proper” and “appropriate,” as the statute requires, will depend on the details of the transaction as proved at trial and under appropriately fashioned instructions to the jury about the law they are to apply so as to understand the questions of fact they are to decide.

*Id.* at 119.

79. Although the court concluded that a failure to comply with the SDE was not an additional element of the offense that must be specifically alleged in the indictment, it also noted that the SDE provides “a framework around which arguments of the parties regarding the evidentiary issues, such as how the government is to prove beyond a reasonable doubt that the defendant acted with the requisite state of mind, may be presented during trial.” *Id.* at 122. Thus, the court noted that evidence that discounts or rebates were disclosed may require evidentiary rulings or a jury instruction regarding the impact of the SDE. *Id.*

80. I am aware of only two other opinions addressing the SDE that were issued during the Alleged Relevant Time Period, both of which were unpublished.<sup>14</sup> These

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<sup>14</sup> See *U.S. ex rel. Bidani v. Lewis*, No. 97 C 6502, 2001 WL 747524 (N.D. Ill. June 27, 2001) (“*Bidani I*”); *U.S. ex rel. Bidani v. Lewis*, No. 97 C 6502, 2001 WL 1609377 (N.D. Ill. Dec. 14, 2001) (“*Bidani II*”). In addition, a subsequent opinion in the *Bidani* case issued during the Relevant Time Period quotes the SDE, but does not substantively

opinions were not issued until mid to late 2001, after the OIG's November 1999 guidance regarding the relevant language in the SDE issued in connection with the RDSH rulemaking, and related to conduct occurring before the November 1999 RDSH rulemaking. These opinions therefore provided little guidance with respect to discounts and rebates in effect after the 1999 RDSH rulemaking that interpreted the relevant language in the SDE, given that the relevant conduct in those cases occurred before that guidance was issued.

(ii) The Regulatory Discount Safe Harbor

81. Based upon my experience, including as Chief of the Industry Guidance Branch of the Office of Counsel to the Inspector General of HHS, it is my opinion that there was clear guidance on the RDSH from the OIG, since as early as November 19, 1999, when the 1999 RDSH became effective. Specifically, the following materials were available and would have been considered in determining whether discounts and rebates such as those contained in the Omnicare Direct Purchase Agreements and GPO Agreements were protected by the RDSH: (a) the regulatory text, the preamble, and the rulemaking history of the RDSH; (b) the available case law; and (c) other relevant OIG guidance, including advisory opinions.

(a) The Regulatory Text and Rulemaking History of the RDSH

82. In addition to the actual text of the RDSH, which is described above in Section IV.A.(iv), the accompanying preambles were available and would have been considered to gain further insight into the regulatory text: the 1989 proposed rule, the Final 1991 Rule, the 1994 proposed clarifications,<sup>15</sup> and the 1999 Clarification

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address either the SDE or the RDSH. *See U.S. ex rel. Bidani v. Lewis*, 264 F. Supp. 2d 612, 614 (N.D. Ill. 2003).

<sup>15</sup> The 1994 proposed clarifications did not raise any issues relevant for the Discounts and Rebates at issue in this case and are therefore not the subject of discussion herein.

and Additional Safe Harbor rulemaking resulting in the 1999 RDSH applicable to discounts and rebates in effect after November 19, 1999.

83. As discussed in Paragraph 37 above, the 1989 proposed rule would have required charge-based suppliers like Omnicare and the Acquired Pharmacies to actually reduce their charges to Medicaid or Medicare by the amount of any discount they received for items or services that were used in providing the Medicaid or Medicare service. *See* Fraud and Abuse OIG Anti-Kickback Provisions, 54 Fed. Reg. 3088, 3093 (proposed Jan. 23, 1989) (to be codified at 42 C.F.R. pt. 1001). The 1991 Final Rule, however, rejected the proposal that charge-based suppliers pass through any discounts or rebates they received to Medicare or Medicaid in order to qualify for the RDSH. *See* OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952, 35980 (July 29, 1991) (to be codified at 42 C.F.R. pt. 1001).

84. Moreover, as discussed in Paragraph 37 above, the OIG made clear in the 1991 RDSH rulemaking that the scope of the SDE's requirement to report and disclose any discount varied depending on whether the purchaser filed a cost report or submitted a charge-based claim. *Id.* With respect to charge-based purchasers, such as Omnicare and the Acquired Pharmacies, the OIG recognized that the requirement that the discount be "appropriately reflected" did not require charge-based suppliers to pass on any discount to Medicare or Medicaid on the claim form. *Id.* In 1999, the OIG once again addressed the SDE requirement that the discount be "properly disclosed and appropriately reflected in the costs claimed or charges made" and determined that charge-based suppliers need not disclose any discounts on their claim forms and also expressly protected rebates to charge-based suppliers. Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statue, 64 Fed. Reg. 63518, 63527 (Nov. 19, 1999) (to be codified at 42 C.F.R. pt. 1001).

(b) Available Case Law Addressing the RDSH

85. There were no reported cases substantively applying or interpreting the RDSH until 2001, by which time the 1999 RDSH had been promulgated and the 1991 RDSH was no longer in effect.

(1) Case Law Addressing the 1999 RDSH

86. Based upon my experience, including as Chief of the Industry Guidance Branch of the Office of Counsel to the Inspector General of HHS, it is my opinion that in addition to the rulemaking history, any relevant case law interpreting the RDSH would have been considered in determining whether the Discounts and Rebates violated the AKS. However, during the relevant time frame, there was little relevant case law. In fact, I am aware of only the following three cases that substantively addressed the 1999 version of the RDSH: (1) *U.S. ex rel. Klaczak v. Consolidated Medical Transport*, No. 96 C 6502, 2002 WL 31010850 (N.D. Ill. Sept. 9, 2002); (2) *United States v. Carroll*, 320 F. Supp. 2d 748 (S.D. Ill. 2004); and (3) *U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235 (3d Cir. 2004). However, as explained below, these three cases addressed discounts and rebates that were significantly different from those at issue here. Moreover, none of these opinions were available – and thus could not provide guidance – to Omnicare before it entered into the 2001 Direct Purchase Agreement. Therefore, these cases could not alter the reasonable conclusion that the Discounts and Rebates were protected by the RDSH.

87. In *U.S. ex rel. Klaczak v. Consolidated Medical Transport*, the court denied the defendants' motion to dismiss, finding that the RDSH did not apply to the arrangement at issue because the defendant ambulance company discounted its rates only for those ambulance services that were paid by the hospital and not for those ambulance services paid by Medicare. See *Klaczak*, 2002 WL 31010850, at \*4. Accordingly, the reduction in price was not a discount as defined in the safe harbor at 42 C.F.R. § 1001.952(h)(5)(iii) ("The term discount does not include . . . [a] reduction in price applicable to one payer but not to Medicare, Medicaid or other Federal health care programs."). *Id.* As such, the court concluded that "because the discount arrangement allegedly contained in the [hospitals and

ambulance company] contracts only provides for a discount to [the hospitals] and not Medicare or Medicaid, the arrangement would not fall into the discount safe harbor.” *Id.* Here, however, Organon did not sell its products to Medicare or Medicaid and the Discounts and Rebates were offered by Organon to Omnicare and the Acquired Pharmacies regardless of the ultimate payer of the pharmaceuticals. Accordingly, the Discounts and Rebates offered by Organon were not subject to the exclusion for “reduction in price applicable to one payer but not to Medicare, Medicaid or other Federal health care programs.” *See* 42 C.F.R. § 1001.952(h)(5)(iii) (1999).

88. The court in *United States v. Carroll*, in considering a motion to dismiss an indictment, held that the RDSH did not apply to the arrangement at issue which involved the sale of enteral products and the lease of enteral pumps. *Carroll*, 320 F. Supp. 2d at 756-57. The defendants were charged with providing an undercover entity with free enteral pumps in order to induce the entity to purchase other enteral products (plastic tubes and food). *Id.* at 751-52. The defendants charged an arbitrary rental fee for the pumps that was offset by an equal reduction in the price of the tubes and food. *Id.* at 752. The defendants argued that their conduct did not violate the AKS because their providing free enteral pumps fell squarely within the RDSH. *See id.* at 756. The court rejected this argument, finding that the RDSH requirements could not be met because, although the defendants could show either (i) a “discount” or (ii) a full and accurate report of the transaction on the invoice, coupon or statement submitted to the buyer, they could not show both. *Id.* First, assuming that the rental fee for the enteral pumps represented the actual transaction for the pumps, the court found that the RDSH would not apply because such an arrangement would be a lease rather than a sale and the RDSH’s definition of a “discount” does not apply to leases. *Id.* at 757. Second, assuming the arrangement involved providing the buyer with a “discount” on the enteral pumps by providing them for \$0, the court found that the RDSH would not apply because the defendants could not show that the discount was fully and accurately reported on the invoice as required by the RDSH, because the invoices provided that a \$5 rental fee was paid for the enteral pumps which was inaccurate if the buyer in fact

paid \$0. *Id.* Here, however, the Discounts and Rebates were not a lease and were accurately reported on the “invoice, coupon or statement.” *See infra* note 21.

89. Finally, although the court in *U.S. ex rel. Schmidt v. Zimmer, Inc.*, cites to both the SDE and RDSH, it appears only to apply the RDSH in conclusory fashion and does not appear to apply the SDE at all. *Schmidt*, 386 F.3d at 235-45. In *Schmidt*, the defendant on appeal “insist[ed] that the Anti-Kickback Act provides a safe harbor for marketing programs offering discounts to health care providers and that its program was designed to take advantage of this safe harbor.” *Id.* at 241.

Although the court acknowledged that “[w]hen the record is fully developed, this may turn out to be the case,” the court rejected the argument given the current posture of the case because the complaint alleged that the contractual incentives and bonuses were paid in “cash and cash equivalents” and thus did not fall within the definition of “discount” in the RDSH. *Id.* Here, however, the Discounts and Rebates at issue were not paid in cash but rather checks, which are expressly permitted by the RDSH. *See* 42 C.F.R. § 1001.952(h)(5)(i) (1999).

(c) Available OIG Guidance Regarding the RDSH

90. In addition to the rulemaking history and case law regarding the RDSH, there was also OIG guidance available that would have been considered in determining whether the Discounts and Rebates were protected by the RDSH.

91. In August 1994, the OIG issued a Special Fraud Alert on Prescription Drug Marketing Practices (“SFA”) that was available during the Relevant Time Period and would have been considered in determining whether the Discounts and Rebates were protected by the RDSH. The SFA identified a number of pharmaceutical company marketing practices with which it was concerned, including an arrangement through which a pharmaceutical company paid “a cash award” to pharmacies for each time a drug prescription was changed from another drug to that pharmaceutical company’s drug. Notably, the arrangement did not involve a “discount” on the price of a drug to a purchaser. Rather, the arrangement at issue involved direct cash payments to pharmacists not in connection with any discount arrangement pursuant to a purchase agreement. Specifically, the

arrangement involved making cash payments to pharmacists for moving their customers from one pharmaceutical to another. The OIG stated that such arrangements involving cash payments for “switching” did not fit in any safe harbor and could violate the AKS. OFFICE OF INSPECTOR GEN., SPECIAL FRAUD ALERT: PRESCRIPTION DRUG MARKETING SCHEMES (Aug. 1994). The OIG emphasized, however, that a payment given for “changing a prescription, or recommending or requesting such a change, from one product to another,” may be lawful if “the payment is made fully consistent with a ‘safe harbor’ regulation, 42 CFR 1001.952, or other Federal provision governing the reporting of prescription drug prices.” OIG Special Fraud Alert, 59 Fed. Reg. 65372, 65376 (Dec. 19, 1994).

92. In addition to the 1994 SFA, OIG Advisory Opinion 98-2, issued April 8, 1998, was available during the Relevant Time Period and would have been considered in determining whether the Discounts and Rebates were protected under the RDSH. OFFICE OF INSPECTOR GEN., OIG ADVISORY OPINION 98-2 (Apr. 8, 1998). OIG Advisory Opinion 98-2 involved a rebate arrangement between a pharmaceutical manufacturer and a wholesaler pursuant to which the rebate was conditioned on the wholesaler’s designation of the manufacturer’s products as “preferred” products and the wholesaler’s promotion of the manufacturer’s drug products to its customers. *Id.* at 2-3. As a threshold issue, the OIG determined that the arrangement could not qualify for protection under the RDSH because the RDSH only applies to discounts to customers that submit claims or cost reports, or have claims submitted in their name, to Medicare or Medicaid, which the wholesaler did not do. *Id.* at 7.

93. The OIG nevertheless found that the discount arrangement “[did] not constitute prohibited remuneration for purposes of the anti-kickback statute.” The OIG explained that:

As a threshold matter, the Proposed Arrangement is substantially similar to the arrangements protected by the current discount safe harbor. The discount under the Proposed Arrangement is applicable to specific transactions for specific products. Although the amount of the rebate to the wholesaler will not be known at the time of sale, the rebate will be available and accounted for by Company A [a generic pharmaceutical manufacturer] in calculating its quarterly “average manufacturer price” or “best price”

(depending on the product) for purposes of determining its Medicaid rebate. In sum, even though the wholesalers do not submit claims to Medicare or Medicaid for these purchases, Company A's disclosures will ensure that the discounts are properly reported and reflected in the Medicaid rebate.

*Id.* at 7-8. Importantly, the OIG implicitly found that if the wholesaler had been submitting claims to Medicare or Medicaid, the arrangement would have qualified for protection under the RDSH because it met the conditions of the RDSH.

94. In OIG Advisory Opinion 98-2, the OIG specifically addressed the requirement that the buyer promote the seller's products to its customers and found that promotion requirement consistent with the SDE and RDSH:

Implicit in any manufacturer's discount to a wholesale purchaser is a financial incentive to the wholesale purchaser to increase its retail sales of the discounted product. That financial incentive does not change simply because the Proposed Arrangement conditions the discount on the performance of certain limited activities that directly support the resale of the Contracted Products.

*Id.* at 9.

95. The 1994 SFA and OIG Advisory Opinion 98-2 were materials available during the Relevant Time Period and addressed arrangements to incentivize persons to promote or recommend a product. Both guidances indicated that so long as the only remuneration being transferred was a reduction in the amount paid for an item or service, the remuneration could qualify for the SDE or RDSH.

(iii) Discounts and Rebates Common in the Industry

96. In determining whether reductions in prices violated the AKS during the Relevant Time Period, industry practices – and specifically whether a particular discount or rebate arrangement comported with the common, usual, and customary practices in the industry – would have been considered, in addition to all of the materials described above. Absent contrary guidance, common practices are presumed lawful. As set forth in Section V.A. above, the Discounts and Rebates at issue in this case were common, usual and customary in the industry during the Relevant Time Period.

(iv) The Intent of the Parties

97. Furthermore, in determining whether reductions in prices violated the AKS after 1980, when the AKS was amended to require “knowing and willful” intent, the intent of the parties in entering into the pricing arrangement at issue would have been considered. Specifically, whether the reduction in price was provided “knowingly and willfully . . . to induce” a person to make or arrange for a referral, or to purchase or recommend purchasing an item or service would be considered. 42 U.S.C. § 1320A-7b(2). Guidance on the intent requirement of the AKS that was available during the Relevant Time Period and would have been considered included the following: (i) the “willful” element of the AKS requires a heightened scienter standard (*United States v. Jain*, 93 F.3d 436, 440 (8th Cir. 1996); *United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20, 33 (1st Cir. 1989)); (ii) the person or entity accused of violating the AKS must act with the intent to disobey or disregard the law, even if the person did not know the specific law being violated (*Bay State Ambulance*, 874 F.2d at 33 (explaining that to act “willfully” is “to do something purposely, with the intent to violate the law, to do something purposely that law forbids”); *United States v. Starks*, 157 F.3d 833, 838-39 (11th Cir. 1998); *Jain*, 93 F.3d at 440-41); and (iii) the “willful” element is satisfied where one purpose of the remuneration is to unlawfully induce referrals (*United States v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989); *United States v. Greber*, 760 F.2d 68, 69 (3rd Cir. 1985), *cert. denied*, 474 U.S. 988 (1985)). In my experience, if this requisite intent was lacking, the person or entity would not be believed to have violated the AKS.

98. In my opinion and based on my experience, including as Chief of the Industry Guidance Branch of the Office of Counsel to the Inspector General of HHS during much of the Relevant Time Period, in attempting to ascertain a party’s intent in entering into an arrangement, there are a number of factors to look at, namely (i) how closely the arrangement conformed to a safe harbor, including the SDE and the RDSH, even if the arrangement did not fit exactly, and (ii) how common, widespread and longstanding were similar arrangements in the industry. With

respect to the former, the closer an arrangement was to a safe harbor, the more likely it would be considered lawful. With respect to the latter, the more common, widespread and longstanding a practice was, the more likely it would be considered lawful. In my opinion and based on my experience, including as Chief of the Industry Guidance Branch of the Office of Counsel to the Inspector General of HHS during much of the Relevant Time Period, arrangements that were close to complying with a safe harbor and that were common and widespread in the industry would be interpreted as lacking characteristics that significantly increased the risk of fraud and abuse compared to safe harbored arrangements and would therefore be viewed as lawful.<sup>16</sup>

C. WHETHER COMPANIES IN THE HEALTH CARE INDUSTRY, EXPERIENCED HEALTH CARE ATTORNEYS AND REGULATORS WOULD HAVE REASONABLY BELIEVED THAT THE DISCOUNTS AND REBATES CONTAINED IN THE OMNICARE DIRECT PURCHASE AGREEMENTS AND THE GPO AGREEMENTS COMPLIED WITH, AND WERE PROTECTED BY, THE STATUTORY DISCOUNT EXCEPTION

(i) The Statutory Discount Exception's Application to the Discounts and Rebates Contained in the Omnicare Direct Purchase Agreements

99. Based on my experience, including as Chief of the Industry Guidance Branch of the Office of Counsel to the Inspector General of HHS during much of the Relevant Time Period, it is my opinion that companies in the health care industry, experienced health care attorneys, and regulators would have reasonably believed that the Discounts and Rebates contained in the Omnicare Direct Purchase Agreements complied with, and were protected by, the SDE during the Relevant Time Period. They would have come to this conclusion based upon the materials identified above in Section V.B., namely (i) the statutory text and legislative history, (ii) the case law available at the time; (iii) the OIG Guidance, including advisory

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<sup>16</sup> See also discussion of OIG's 1991 press briefing on the safe harbors discussed *infra* at Paragraph 144 during which OIG addressed technical noncompliance with a safe harbor.

opinions, and (iv) a consideration of discounts and rebates common in the industry.<sup>17</sup>

100. At all times relevant hereto, companies in the health care industry, experienced health care attorneys, and regulators understood that in order to qualify for the SDE, all discounts had to be “properly disclosed and appropriately reflected in the costs claimed or charges made.” In 1999, the OIG specifically interpreted the SDE’s phrase “properly disclosed and appropriately reflected” and made clear that charge-based buyers did NOT have to (a) pass on the discount in the charge submitted (based on OIG’s interpretation of “appropriately reflected” in 1991 that was reaffirmed in 1999), or (b) report the discount on the claim form submitted for any items (based on OIG’s interpretation of “properly disclosed” in 1999). As noted above, in 1999, the OIG again addressed the “properly disclosed” requirement for charge-based suppliers to eliminate the requirement that the discount be disclosed on the claim form for separately reimbursable items.

101. Based on all of the above, experienced health care attorneys reasonably believed that at least as early as November 19, 1999, when the OIG most recently interpreted the relevant statutory language, charge-based suppliers had no affirmative disclosure obligations in order to qualify for the SDE; that all that was required was that charge-based suppliers provide accurate information to HHS and a state Medicaid agency if such information was specifically requested; and that there were no other conditions required of charge-based suppliers to qualify for protection under the SDE.

102. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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<sup>17</sup> For the same reasons that follow, companies in the health care industry, experienced health care attorneys, and regulators would have reasonably believed that the Discounts and Rebates contained in the Acquired Pharmacies’ Purported Direct Purchase Agreements complied with, and were protected by, the SDE during the Relevant Time Period.

[REDACTED]

[REDACTED] As explained above, in OIG Advisory Opinion 98-2, the OIG specifically acknowledged that an arrangement requiring “the performance of certain limited activities that directly support the resale of the Contracted Products” does not render the arrangement unlawful. OFFICE OF INSPECTOR GEN., OIG ADVISORY OPINION 98-2 at 9 (Apr. 8, 1998). In addition, the Discounts and Rebates contained in the Omnicare Direct Purchase Agreements were consistent with the usual and customary practices in the industry, as set forth in greater detail above in Section V.A.

103. Companies in the health care industry, experienced health care attorneys, and regulators therefore would have concluded that the Discounts and Rebates satisfied all of the elements of the SDE, were not “remuneration” within the meaning of the AKS, and thus not subject to the prohibition of the AKS.

104. As noted above, there were no cases that substantively addressed the application of the SDE until after the promulgation of the 1999 RDSH. The only cases during the Alleged Relevant Time Period that I am aware of that addressed the application of the SDE to any extent were *Shaw* and *Bidani I* and *Bidani II*. As explained more fully above, *Shaw* simply addressed whether the government had to allege a failure to comply with the SDE in an indictment charging a violation of the AKS. Nothing in *Shaw* addressed what kind of a disclosure, if any, had to be made by a charge-based supplier such as Omnicare and the Acquired Pharmacies in order for the SDE to apply. Nor was there anything in *Shaw* that questioned the OIG’s interpretation of the statutory disclosure obligation of a supplier as set out in the preambles to the RDSH.

105. Both *Bidani I* and *Bidani II* addressed the applicability of the SDE and the 1991 version of the RDSH to pre-November 19, 1999 conduct, which is prior to the Relevant Time Period, and were not decided until 2001 – after the 1999 RDSH was promulgated. However, *Bidani II* makes clear that for conduct arising after November 1999, disclosure is not an affirmative requirement of either the SDE or RDSH except upon request by an appropriate government agency. For the reasons discussed above, companies in the health care industry, experienced health care

attorneys and regulators would have had no reason to believe that the Discounts and Rebates were unlawful.

(ii) The Statutory Discount Exception's Application to the Discounts and Rebates Contained in the GPO Agreements

106. Based on my experience, including as Chief of the Industry Guidance Branch of the Office of Counsel to the Inspector General of HHS during much of the Relevant Time Period, it is my opinion that, for the same reasons that companies in the health care industry, experienced health care attorneys and regulators would have reasonably believed that the Discounts and Rebates contained in the Direct Purchase Agreements complied with, and were protected by, the SDE during the Relevant Time Period, they would have reasonably believed that the Discounts and Rebates contained in the GPO Agreements complied with, and were protected by, the SDE during the Relevant Time Period.

107. [REDACTED]

108. As discussed above, both the 1994 SFA and Advisory Opinion 98-2 suggested that a properly structured discount arrangement could be protected even if the arrangement required the buyer to engage in promotional activities. The SFA indicated that a discount for "changing a prescription, or recommending or requesting such a change, from one product to another" could qualify for the SDE or the RDSH. Thus, companies in the health care industry, experienced health care counsel and regulators understood the SFA to stand for the proposition that an arrangement that might directly or indirectly incentivize a customer to promote one product over another or even to switch a patient from one drug to another could qualify for the SDE and would be lawful.

109. Similarly, in Advisory Opinion 98-2, the OIG reviewed certain limited activities that directly support the resale of the products at issue – including the wholesaler making the product its “preferred generic” – and found that the proposed arrangement would not constitute prohibited remuneration under the AKS. In short, Advisory Opinion 98-2 confirmed the industry’s understanding that the SFA did not apply to discounts that qualified for the SDE or RDSH and that discounts could be made contingent on a buyer’s undertaking promotional activities on behalf of a product to its customers.

110. Companies in the health care industry, experienced health care attorneys, and regulators would have understood that the [REDACTED] [REDACTED] qualified for protection under the SDE. As discussed above, in 1999, the OIG specifically interpreted the SDE’s phrase “properly disclosed and appropriately reflected” and made clear that charge-based buyers did NOT have to (a) pass on the discount in the charge submitted (based on OIG’s interpretation of “appropriately reflected” in 1991 that was reaffirmed in 1999), or (b) report the discount on the claim form for any items (based on OIG’s interpretation of “properly disclosed” in 1999). As with the other Discounts and Rebates, the terms of [REDACTED] were fixed in advance, the contract set out the methodology for determining the amount of the discount, and Omnicare and the Acquired Pharmacies had no reporting requirements with respect to discounts. Thus, the [REDACTED] were “properly disclosed and appropriately reflected” as interpreted by the OIG, the agency with expertise in the AKS. The SDE required nothing else.

D. WHETHER COMPANIES IN THE HEALTH CARE INDUSTRY, EXPERIENCED HEALTH CARE ATTORNEYS AND REGULATORS WOULD HAVE REASONABLY BELIEVED THAT THE DISCOUNTS AND REBATES CONTAINED IN THE OMNICARE DIRECT PURCHASE AGREEMENTS AND THE GPO AGREEMENTS COMPLIED WITH, AND WERE PROTECTED BY, THE 1999 REGULATORY DISCOUNT SAFE HARBOR

(i) The 1999 Regulatory Discount Safe Harbor's Application to the Discounts and Rebates Contained in the Omnicare Direct Purchase Agreements

111. Based on my experience, including as Chief of the Industry Guidance Branch of the Office of Counsel to the Inspector General of HHS during much of the Relevant Time Period, it is my opinion that companies in the health care industry, experienced health care attorneys and regulators would have reasonably believed that the Discounts and Rebates contained in the Omnicare Direct Purchase Agreements complied with, and were protected by, the 1999 RDSH (the RDSH that was effective during the entire time period of Omnicare's Direct Purchase Agreements).<sup>18</sup> They would have come to this conclusion based upon the materials identified above in Section V.B., namely (i) the regulatory text, (ii) the preamble and rulemaking history, (iii) available case law, (iv) available OIG Guidance, including advisory opinions and the SFA discussed above, and (v) a consideration of discounts and rebates common in the industry.

112. [REDACTED]  
[REDACTED] s noted above, in OIG Advisory Opinion 98-2, the OIG specifically acknowledged that an arrangement requiring "the performance of certain limited activities that directly support the resale of the Contracted Products" does not render the arrangement unlawful. OFFICE OF INSPECTOR GEN., OIG ADVISORY OPINION 98-2 at 9 (Apr. 8, 1998). In addition, the Discounts and Rebates contained in the Omnicare Direct Purchase

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<sup>18</sup> For the same reasons that follow, companies in the health care industry, experienced health care attorneys, and regulators would have reasonably believed that the Discounts and Rebates contained in the Acquired Pharmacies Purported Direct Purchase Agreements complied with, and were protected by, the 1999 RDSH.

Agreements were consistent with the usual and customary discount and rebate practices in the industry, as set forth in greater detail above in Section V.A.

113. Companies in the health care industry, experienced health care attorneys, and regulators therefore would have concluded that the Discounts and Rebates satisfied all of the elements of the 1999 RDSH. They would have reasonably concluded that the Discounts and Rebates, having satisfied the elements of the 1999 RDSH, were not “remuneration” within the meaning of the AKS and thus not subject to the prohibition of the AKS.

(a) Companies in the Health Care Industry, Experienced Health Care Attorneys, and Regulators Would Have Reasonably Believed That The Two Requirements of the Regulatory Discount Safe Harbor Were Satisfied

114. Companies in the health care industry, experienced health care attorneys, and regulators would have reasonably believed that Omnicare satisfied the requirements for a charge-based supplier to qualify for the RDSH with respect to the Discounts and Rebates at issue so long as: (i) the terms of any discount or rebate were fixed and disclosed in writing to Omnicare at the time of the initial sale of the good or service; and (ii) Omnicare provided, upon request by the Secretary or a State agency, full and accurate disclosure of any pricing information provided by Organon pursuant to 42 C.F.R. § 1001.952(h)(1)(iii) (1999). They would have reasonably believed that there were no other conditions required to qualify for the RDSH.

115. It is my opinion that companies in the health care industry, experienced health care attorneys, and regulators would have reasonably believed that the Omnicare Direct Purchase Agreements satisfied both of these relevant requirements of the RDSH. First, the terms of the Discounts and Rebates were “fixed” given that they were not subject to change without additional written agreement. The Omnicare Direct Purchase Agreements expressly set out all of the terms of the Discounts and Rebates and how the Discounts and Rebates would be calculated at the time the parties entered into the agreements, as required by 42

C.F.R. §1001.952(h)(1)(iii)(A) (1999).<sup>19</sup> As such, the terms of the Discounts and Rebates were “fixed and disclosed in writing” as required by the RDSH.

116. The RDSH requires nothing more and sets no restrictions on how to calculate a discount or rebate or on what conditions are necessary to earn the discount or rebate. So long as the only “remuneration” is a reduction in the amount paid by the buyer for the goods (*i.e.*, there is no other remuneration in the form of cash payments, free goods or services), the regulation set no limits on what kind of activities could trigger the discount or rebate. The understanding among the health care bar and industry was that, as long as an arrangement satisfied the elements relevant to the party’s role (*e.g.*, a buyer submitting charges), the arrangement was protected. At all relevant times, there was no guidance or suggestion from the government that there were any other unwritten requirements or conditions to the RDSH.

117. In the regular course of my legal practice, including before, during and after my service at OIG, I regularly reviewed market share rebate arrangements virtually identical to those contained in the Omnicare Direct Purchase Agreements for compliance with the RDSH and concluded and advised that they satisfied the elements of the RDSH and were protected. At all times, it was my understanding that such market share rebate arrangements qualified for the RDSH. While in the

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Nevertheless, as explained below in Section V.E., even if an arrangement does not fall within the requirements of the SDE or the RDSH, experienced health care attorneys, regulators and companies would not necessarily conclude that the arrangement was unlawful, but instead would consider whether the arrangement posed a risk of fraud. Based upon such a consideration, experienced health care attorneys, regulators and companies would not reasonably conclude that

violated the AKS because it would not raise a risk of fraud. In such a case, the retroactivity would not affect the supplier’s charges to the program or its reporting obligations. In such circumstances, experienced health care lawyers, regulators, and companies assumed that since the arrangement posed no greater risk than the safe harbored arrangements, it would be lawful, as well.

OIG, I regularly provided informal, non-binding advice to the public that market share rebates like the ones contained in the Omnicare Direct Purchase Agreements were protected by the RDSH.

118. Second, I understand that Omnicare responded fully and accurately to any and all government requests for pricing information for Remeron tablet or Remeron SolTab as required by 42 C.F.R. § 1001.952(h)(1)(iii)(B) (1999).

119. Accordingly, companies in the health care industry, experienced health care attorneys, and regulators would have concluded that Omnicare satisfied the requirements for the RDSH protection of the Discounts and Rebates and would have understood that nothing else was required for Omnicare to qualify for that protection.

(b) Companies in the Health Care Industry, Experienced Health Care Attorneys, and Regulators Would Have Reasonably Believed That The Discounts And Rebates Met The Definition Of “Discount” In The Regulatory Discount Safe Harbor

(1) The RDSH’s Definitions of “Discount” and “Rebate”

120. Companies in the health care industry, experienced health care attorneys, and regulators would have considered the definition of “discount” and “rebate” in the RDSH in determining whether the Discounts and Rebates at issue were protected. The RDSH defines a “discount” as “a reduction in the amount a buyer . . . is charged for an item or service based on an arms-length transaction.” 42 C.F.R. § 1001.952(h)(5) (1999). All of the discounts in the Omnicare Direct Purchase Agreements were reductions in the amount the purchaser would pay for the relevant drugs purchased; there were no cash payments or free goods or services provided. Moreover, the Omnicare Direct Purchase Agreements (and the GPO Agreements) were arms-length transactions. To my knowledge, Organon was independent from Omnicare and the Acquired Pharmacies and Organon was not under any compulsion to sell the pharmaceuticals to those pharmacies. Similarly,

neither Omnicare nor the Acquired Pharmacies were under any compulsion to purchase pharmaceuticals from Organon.

121. The RDSH defines a “rebate” as “any discount the terms of which are fixed and disclosed in writing to the buyer at the time of the initial purchase to which the discounts applies, but which is not given at the time of sale.” 42 C.F.R. § 1001.952(h)(4) (1999). The rebates contained in the Omnicare Direct Purchase Agreements and [REDACTED] satisfied this condition, as explained more fully in Paragraph 115 above.<sup>20</sup>

122. Before, during and after my service with the OIG, I understood and advised clients and the public that so long as the “remuneration” that was transferred between the seller and buyer was a reduction in the price of a good or item sold, that “remuneration” qualified as a “discount” or a “rebate” for purposes of the RDSH unless otherwise excluded. It is my opinion that that view was shared by experienced health care practitioners and regulators.

(2) Exclusions from the RDSH’s Definition of “Discount”

123. Companies in the health care industry, experienced health care attorneys, and regulators would have considered whether the Discounts and Rebates were otherwise excluded from the definition of a discount in the RDSH under 42 C.F.R. § 1001.952(h)(5)(i)-(vii) (1999). The RDSH provides that a discount does not include: (i) cash payments other than rebate checks; (ii) the giving of a free or discounted price on one good that is conditioned on the purchase of another good except if the goods are reimbursed using the same reimbursement methodology; (iii) a price reduction to one payer but not to Medicare, Medicaid or other federal payers; (iv) a routine waiver of coinsurance; (v) warranties; (vi) services pursuant to a personal or management services contract; and (vii) other remuneration in

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<sup>20</sup> See footnote 19, *supra*, explaining that, [REDACTED] experienced health care attorneys, regulators and companies would not necessarily conclude that [REDACTED] were unlawful.

cash or in kind that is not explicitly described above. 42 C.F.R. § 1001.952(h)(5) (1999).

124. Companies in the health care industry, experienced health care attorneys, and regulators would have reasonably believed that none of the exclusions in the discount definition would have applied to the Discounts and Rebates contained in the Omnicare Direct Purchase Agreements. Rebate checks, such as those paid under the terms of the Discounts and Rebates at issue,<sup>21</sup> were specifically permitted by the regulations. In addition, as deposition testimony has confirmed, the Discounts and Rebates were fully set forth in the contracts and were not tied to the purchase of other goods or services or any other arrangements outside the four corners of the contracts.<sup>22</sup> The contracts did not relate to any routine waiver of coinsurance and the Discounts and Rebates were not pursuant to a management or personal services contract. The Discounts and Rebates consisted solely of a reduction in the amount Omnicare was charged for Remeron tablet and/or Remeron SolTab according to the terms of the contract as explicitly described in the RDSH's definition of discount.

125. Further, the Discounts and Rebates were not excluded price reductions given to one payer but not to government payers. *See* 42 C.F.R. § 1001.952(h)(5)(iii) (1999). Based upon my experience, experienced health care attorneys, regulators and companies would have understood that this language requires that a seller that sells (or submits claims) directly to Medicare and Medicaid, as well as to commercial buyers, must offer Medicare and Medicaid at least the same discounts offered to other commercial buyers for the same items or services. For example, in *Klaczak*, the ambulance company was giving a discount to the hospitals for the same ambulance services that it was billing to Medicare at full price. *See Klaczak*,

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<sup>21</sup> *See, e.g.* Tr. of John Maddox Nov. 4, 2013 Dep. ("Maddox Tr.") at 243:24-247:25 (explaining the process of how rebates were calculated and documented and how rebate checks were issued from Organon to Omnicare); BA-JBET-000841-853 (an example of rebate documentation and copies of rebate checks discussed during Maddox's deposition).

<sup>22</sup> *See, e.g.*, Maddox Tr. at 240:3-8, 242:25-243:8.

2002 WL 31010850, at \*4. *See also* OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952, 35977 (July 29, 1991) (to be codified at 42 C.F.R. pt. 1001) (“[W]e believe that Congress did not intend for this discount exception to apply to price reductions offered to one payor but not to Medicare or Medicaid. For example, we are aware of cases where laboratories offer a discount to physicians who then bill the patient, but do not offer the same discount to the Medicare program.”).

126. Organon, however, does not sell or submit claims for Remeron tablet or Remeron SolTab directly to Medicare or Medicaid. Rather, Organon sells only to entities that in turn sell or bill items or services to commercial patients and federal health care enrollees. The Discounts and Rebates are offered to Omnicare regardless of the identity of the ultimate payor. Accordingly, companies in the health care industry, experienced health care attorneys, and regulators would have reasonably believed that the Discounts and Rebates in the Omnicare Direct Purchase Agreements were not excluded by 42 C.F.R. § 1001.952 (h)(5)(iii) (1999).

(c) Companies in the Health Care Industry, Experienced Health Care Attorneys And Regulators Would Have Reasonably Believed That The Regulatory Discount Safe Harbor Did Not Require Charge-Based Buyers To Affirmatively Report Or Directly Pass On Discounts To Medicaid

127. In reaching the conclusion that the 1999 RDSH did not require charge-based suppliers to affirmatively report or directly pass on discounts and rebates received to Medicare, Medicaid or other federal health care programs, experienced health care attorneys, regulators and companies would have considered the clear and unambiguous statements by the OIG to that effect.

128. Specifically, experienced health care attorneys, regulators and companies would have considered the initial 1989 proposed RDSH, in which the OIG proposed to require charge-based buyers like Omnicare and the Acquired Pharmacies to reduce its charges to Medicare and Medicaid to reflect any discount it would have received on a specific pharmaceutical. Fraud and Abuse OIG Anti-Kickback Provisions, 54 Fed. Reg. 3088, 3093 (proposed Jan. 23, 1989) (“[T]hose paid in

whole or in part on the basis of charges, the exemption applies only if the discount is reported, and the actual charge is reduced by the full amount of the discount”). In the Final 1991 RDSH, however, the OIG expressly rejected its proposal that charge-based suppliers must pass through any discounts or rebates they received to Medicare or Medicaid in order to qualify for the RDSH. OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952, 35980 (July 29, 1991) (to be codified at 42 C.F.R. pt. 1001) (“We . . . are revising paragraph (h)(1)(iii) of this safe harbor provision to delete the requirement that charge-based health care providers reduce their charges by the full amount of the discount.”). Thus, it is clear that suppliers like Omnicare and the Acquired Pharmacies are not required to pass on any discounts to Medicare or Medicaid.

129. In my opinion, companies in the health care industry, health care attorneys and regulators understood the 1999 RDSH and its preamble to confirm that suppliers like Omnicare and the Acquired Pharmacies have no affirmative obligation to report any discount to Medicare or Medicaid in order to qualify for the RDSH. Instead, in order to qualify for the RDSH, a charge-based buyer need only report any discount received if it receives a specific request from federal or state regulators. That understanding was consistent with experienced health care counsel and regulators.

130. Since at least November 19, 1999, I have regularly advised clients and the public that the RDSH did not require that a charge-based supplier like Omnicare and the Acquired Pharmacies pass on a discount or rebate it may have received to Medicare, Medicaid, or other federal health care program or report the amount of any discount or rebate received, unless specifically requested by the federal or a state government agency.

131. The 1999 RDSH extended the protection of the RDSH to rebates offered by charge-based suppliers. Thus, since at least November 19, 1999 (and thus prior to the effective date of the first Omnicare Direct Purchase Agreement), it was reasonable to conclude that the RDSH applied to rebates.

(ii) The 1999 Regulatory Discount Safe Harbor's Application to the Discounts and Rebates Contained in the GPO Agreements

132. For the same reasons that companies in the health care industry, experienced health care attorneys, and regulators would have reasonably believed that the Discounts and Rebates contained in the Omnicare Direct Purchase Agreements complied with, and were protected by, the 1999 RDSH, they would have also reasonably believed that the Discounts and Rebates contained in the GPO Agreements complied with, and were protected by, the 1999 RDSH.

133. The RDSH expressly protects discounts given directly by the seller to the purchaser and those given indirectly to the purchasers through a GPO. 42 C.F.R. § 1001.952(h)(5) (1999) ("the term discount means a reduction in the amount a buyer (who buys either directly or through a wholesaler or a group purchasing organization) is charged for an item or service").

134. Companies in the health care industry, experienced health care counsel and regulators would have understood that [REDACTED]

[REDACTED] qualified for the RDSH. As with the other Discounts and Rebates, the terms of [REDACTED] were fixed in advance and [REDACTED]

[REDACTED] The RDSH required nothing else. Nothing in the RDSH restricts the conditions necessary to earn the rebate other than a discount may not be conditioned on the purchase of another product, unless both products were reimbursed under the same reimbursement methodology. *See* 42 C.F.R. § 1001.952(h) (1999).

135. Discounts, including rebates, are often used to incentivize buyers to purchase a manufacturer's pharmaceuticals. There is nothing in the regulatory text or the rulemaking preambles that suggested that such discounts might not qualify for the RDSH. So long as the only remuneration being transferred was a reduction in the amount paid for an item or service, it made no difference whether the remuneration was to induce the purchaser to buy the product or to promote or recommend the product or both.

136. Companies in the health care industry, experienced health care attorneys, and regulators would have considered the common industry understanding reflected in OIG Advisory Opinion 98-2 discussed more fully above in assessing the

As explained above, Advisory Opinion 98-2 concerned a discount arrangement between a manufacturer of pharmaceutical products and a wholesaler that was conditioned on the buyer taking certain actions to promote the seller's products to the buyer's customers. The OIG concluded that the discount arrangement at issue would not be subject to sanctions by the OIG. The OIG noted that:

[I]mplicit in any manufacturer's discount to a wholesale purchaser is a financial incentive to the wholesale purchaser to increase its retail sales of the discounted product. That financial incentive does not change simply because the Proposed Arrangement conditions the discount on the performance of certain limited activities that directly support the resale of the Contracted Products.

OFFICE OF INSPECTOR GEN., OIG ADVISORY OPINION 98-2 at 9 (Apr. 8, 1998).

137. The OIG's statement in Advisory Opinion 98-2 was also consistent with its previous SFA, reprinted at 59 Fed. Reg. 65372 on December 19, 1994. The fraud alert addressed several arrangements in which a pharmaceutical manufacturer offered a cash award to physicians and pharmacists on a per prescription or per switch basis. The OIG observed that the specific arrangement at issue involving cash payments in exchange for the service of "switching" did not fit in any safe harbor, but acknowledged that a payment made for changing or recommending a change in a prescription from one product to another could be okay if "the payment is made fully consistent with a 'safe harbor' regulation, 42 CFR 1001.952, or other Federal provision governing the reporting of prescription drug prices." 59 Fed. Reg. 65372, 65376 (emphasis added). In other words, the OIG advised that such arrangements could be structured to fit in the RDSH. For example, if the arrangement was sanctioned as a discount or rebate rather than a cash payment (something that is specifically excluded from the RDSH, see 42 C.F.R. § 1001.952(h)(5)(i)), such an arrangement could be protected by the RDSH.

138. Before, during and after my OIG service, I regularly advised clients and the public that conditioning discounts on a buyer's undertaking promotional activity related to the purchased product was permissible under the RDSH provided that the remuneration consisted solely of a price reduction in the amount charged the customer for the goods and the other relevant terms of the RDSH were satisfied. Those activities could include therapeutic interchange programs and preferred formulary placement for the pharmaceutical. Based on my experience, it is my opinion that my views were consistent with experienced health care counsel and regulators.

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139. Accordingly, because (i) the Discount and Rebate arrangements in the Omnicare Direct Purchase Agreements and the GPO Agreements qualified as discounts or rebates within the terms of the Regulatory Discount Safe Harbor; (ii) the terms were fixed and disclosed in writing in the Omnicare Direct Purchase Agreements and the GPO Agreements; and (iii) Omnicare and the Acquired Pharmacies, as charge-based suppliers, had no other obligations absent a government request, experienced health care counsel, regulators and companies would have reasonably believed that the Discounts and Rebates qualified for the protection of the 1999 RDSH. I certainly would have.

E. WHETHER COMPANIES IN THE HEALTH CARE INDUSTRY, EXPERIENCED HEALTH CARE ATTORNEYS, AND REGULATORS REASONABLY WOULD HAVE BELIEVED THAT THE DISCOUNTS AND REBATES CONTAINED IN THE OMNICARE DIRECT PURCHASE AGREEMENTS AND THE GPO AGREEMENTS DID NOT VIOLATE THE AKS DURING THE RELEVANT TIME PERIOD

140. Companies in the health care industry, experienced health care attorneys, and regulators would have reasonably believed that the Discounts and Rebates contained in the Omnicare Direct Purchase Agreements and the GPO Agreements did not violate the AKS during the Relevant Time Period.<sup>23</sup>

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<sup>23</sup> For the same reasons that follow, companies in the health care industry, experienced health care attorneys, and regulators would have reasonably believed

141. The materials that would be considered by companies in the health care industry, experienced health care attorneys, and regulators as described more fully above would not provide a reasonable basis to believe that the Discounts and Rebates violated the AKS or were outside the protection afforded by the SDE and the RDSH.

142. If companies in the health care industry, experienced health care attorneys, and regulators had in fact concluded that the Discounts and Rebates did not fit within either the SDE or the RDSH (or both), they would not necessarily conclude that the Discounts and Rebates were unlawful. Rather, they would consider, among other things, whether the parties intended to violate the AKS, based on the available guidance on the requisite intent, as discussed more fully in Section V.B.(iv) above. I have not seen anything in the materials that I have reviewed as cited herein (and/or as set forth in Exhibit 3) that would provide companies in the health care industry, experienced health care attorneys, or regulators with a reasonable basis to conclude that Omnicare and/or the Acquired Pharmacies unlawfully, intentionally and willfully intended to violate the AKS by entering into the agreements with Organon for the Discounts and Rebates.

143. In particular, companies in the health care industry, experienced health care attorneys, and regulators consider how close a particular arrangement is to a safe harbor in determining whether an arrangement violates the AKS. Arrangements that substantially comply with a safe harbor, but for minor or insubstantial reasons that do not raise the arrangement's risk profile, are considered not to raise any serious risk of fraud or abuse concerns and are not viewed as unlawful under the AKS.

144. Indeed, the OIG has long indicated that a failure to meet all the conditions of a safe harbor does not mean that the arrangement violates the AKS. In 1991, when it promulgated the initial safe harbors, the OIG addressed substantial compliance with a safe harbor. At a press briefing on the safe harbors, the OIG stated:

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that the Discounts and Rebates contained in the Acquired Pharmacies Purported Direct Purchase Agreements did not violate the AKS during the Relevant Time Period.

Now, we are frequently asked sometimes, “What if we are close to a safe harbor? What if we’re in compliance with seven out of eight standards for the small entity investment safe harbor?”

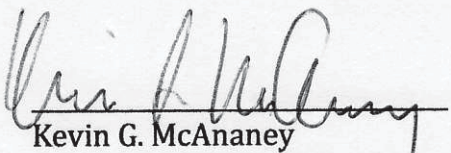
The answer to that question, of course, depends on how it is that you’re not in the safe harbor. If you are complying with seven out of eight standards but you are paying a twenty dollar fee to anyone who refers a patient to you, you have a problem, notwithstanding the fact that you may be close to the safe harbor. *On the other hand, it is not our intent to crack down on those who are only in technical noncompliance or only have a very insubstantial difference from the safe harbor.*

“Briefing by The Office of Inspector General Safe Harbor Regulations,” Briefing by D. McCarty Thornton & Thomas Crane, Aug. 6, 1991, at 5 (emphasis added).

145. I have not seen anything in the materials that I have reviewed as cited herein (and/or as set forth in Exhibit 3) that would provide companies in the health care industry, experienced health care attorneys, or regulators with a reasonable basis to conclude that the Discounts and Rebates presented any greater risk of fraud or abuse than discounts and rebates that fit in the 1999 RDSH.

146. Similarly, companies in the health care industry, experienced health care attorneys, and regulators consider how common, widespread and longstanding were similar arrangements in the industry. Arrangements that are common, widespread and longstanding in the industry are considered not to raise any serious risk of fraud or abuse concerns and are not viewed as unlawful under the AKS. As discussed above in Section V.A., the Discounts and Rebates are common, usual and customary in the industry during the Relevant Time Period. I have not seen anything in the materials that I have reviewed as cited herein (and/or as set forth in Exhibit 3) that would provide companies in the health care industry, experienced health care attorneys, or regulators with a reasonable basis to conclude that the Discounts and Rebates differed materially from those that are common, usual and customary in the industry and thus presented any greater risk of fraud or abuse than such common, usual and customary discounts and rebates.

Highly Confidential, Subject to Protective Order



Kevin G. McAnaney  
Executed July 2, 2015

**EXHIBIT 1**

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**2003 – Present**

**LAW OFFICES OF KEVIN G. MCANANEY**  
New York, NY

Established boutique health care law practice, focusing on the regulation of fraud and abuse.

**1997 - 2003**

**CHIEF, INDUSTRY GUIDANCE BRANCH**  
Office of Counsel to The Inspector General  
U.S. Department of Health And Human Services  
Washington, D.C.

Joined government after fourteen years in private law practice to set up new IG function to coordinate and issue guidance to the health care industry related to health care fraud and abuse, including advisory opinions, special fraud alerts, and regulatory “safe harbors” to the federal anti-kickback statute. Recruited and supervised four experienced health care lawyers from private sector. Worked closely with HCFA (now CMS) and Department of Justice in developing and issuing guidance through advisory opinions, special fraud alerts, informal letters and rulemaking. Developed final rule implementing the Ethics in Patient Referrals Act (also known as “Stark II”), published January 2001. Worked closely with DoJ on criminal and civil prosecutions involving the anti-kickback statute and other fraud and abuse laws. Frequent speaker at industry conferences.

**1986 -1997**

**PARTNER, DEWEY BALLANTINE**  
Washington, D.C.

Developed general regulatory and transactional practice in the health care, food and drug, and environmental areas. Represented various clients, including physicians, medical device and pharmaceutical manufacturers, hospital and health care companies, health care trade associations and investment companies underwriting health care companies’ public offerings. Developed and headed firm’s environmental practice, primarily in Superfund litigation. Worked closely with Joseph Califano, the former Secretary of the Department of Health, Education and Welfare, and head of the firm’s Washington, D.C. office.

**EXHIBIT 1**

**1983 - 1986**

**ASSOCIATE, DEWEY BALLANTINE**  
Washington, D.C.

Worked as associate on various regulatory and transactional matters in the health care, food and drug, and environmental areas.

**1981 - 1983**

**ASSISTANT COUNSEL TO GOVERNOR HUGH CAREY**  
Albany, New York

Responsible for developing, coordinating and negotiating the Governor's legislative program in the health and human services areas, including the passage of legislation establishing the nation's first all payer hospital prospective payment system and securing waiver from the U.S. Department of Health, Education and Welfare to include Medicare and Medicaid participation in the reimbursement system. Responsible for coordinating the legislative programs of the State's health and human services agencies. Represented and advised the Governor with respect to other legislation in the health and human services areas. Coordinated activities of State health and human services agencies that affected more than one agency. Developed proposal that resulted in creation of the Governor's Task Force on Life and the Law, a panel consisting of industry, religious and political leaders to develop consensus on medico-legal issues, such as withdrawal of treatment and the definition of death.

**1980 - 1981**

**ASSOCIATE, KELLEY DRYE & WARREN**  
**Director of Legal Affairs, The New York Hospital**  
New York, New York

Staffed the Office of Legal Affairs for The New York Hospital, one of the largest teaching hospitals in the country. Responsible for the initial intake, evaluation and coordination of all legal matters affecting the Hospital on a daily basis. Provided general advice relating to medical malpractice, medical staff relations, informed consent, State regulatory matters, and other miscellaneous legal issues.

**1977 - 1980**

**ASSOCIATE, KELLEY DRYE & WARREN**  
New York, New York

Litigation Associate. Researched and drafted legal memoranda, briefs and pleadings.

**EDUCATION:** Phillips Exeter Academy (diploma, 1967)

**EXHIBIT 1**

B.A., University of North Carolina at Chapel Hill, 1971  
J.D., Columbia University School of Law, 1977

**KEVIN MCANANEY**

EXPERT WITNESS TESTIMONIAL/DEPOSITION EXPERIENCE (Last Four Years)

1. United States ex rel Jamison v. McKesson Corp, et al, United States District Court, Northern District of Mississippi, Case No. 2:08cv0214-SA-DAS, Deposition
2. Pittsburgh SNF, LLC, et al. v. Pharmerica East, Inc., United States District Court, Eastern District of Texas (Marshall Div.), Case No. 2:10-CV-363, Deposition
3. United States ex rel. Jon Willem Pasqua, et al. v. Kan-Di-Ki, LLC, United States District Court, Central District of California, Case No. 2:10-CV-00965-JST-RZ, Deposition
4. Carl Sullivan v. Midatlantic Cardiovascular Associates, P.A., et al., Circuit Court of Maryland, Baltimore County, Case No. 03-c-10-012624MM, Deposition
5. United States ex rel. Kevin P. McDonough v. Symphony Diagnostic Services, Inc. et al, United States District Ct., Southern Dt. Ohio, Case No. 2:08-CV-0014, Deposition
6. Arthrex, Inc. and Arthrex Manufacturing, Inc. v. Parcus Medical LLC, U.S.D.C. Middle Dt. FL, Case No. 2:11-cv-694-FtM-29UAM, Deposition
7. Hanks v. Amgen, Superior Ct, Ventura Cty. CA, Case 56-2009-00342748, Deposition
8. United States ex rel. Swetnam v. Valley Baptist Health System et al., United States District Court for the Southern District of Texas, Civil Action No. 8-08-446, Deposition
9. United States ex rel. Robinson-Hill v. Nurses Registry and Home Health Corp., et al., United States District Court for the Eastern District of Kentucky, CA No. 08:145, Deposition
10. Robert F. Valentz, M.D. v. The Surgery Center of Fairbanks, LLC, Commercial Arbitration, Testimony

**MATERIALS REVIEWED**

1. Social Security Act Titles XI, XVIII, XIX
2. Medicare-Medicaid Anti-Fraud and Abuse Amendments, Pub. L. 95-142, 91 Stat. 1175 (1977)
3. H.R. Rep. No. 95-393 pt. 2 (1977), *reprinted in* 1977 U.S.C.C.A.N. 3039
4. Omnibus Reconciliation Act of 1980, Pub. L. 96-499, 94 Stat. 2599 (1980)
5. H.R. Rep. No. 96-1167 (1980), *reprinted in* 1980 U.S.C.C.A.N. 5526
6. Medicare-Medicaid Patient and Program Protection Act of 1987, Pub. L. 100-93, 101 Stat. 680 (1987)
7. H.R. Rep. No. 100-109 (1987), *reprinted in* 1987 U.S.C.C.A.N. 682
8. S. REP. NO. 95-453, at 12 (1977)
9. 42 C.F.R. § 1001.952
10. Fraud and Abuse OIG Anti-Kickback Provisions, 54 Fed. Reg. 3088 (proposed Jan. 23, 1989) (to be codified at 42 C.F.R. pt. 1001)
11. OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952 (July 29, 1991) (to be codified at 42 C.F.R. pt. 1001)
12. Clarification of the OIG Safe Harbor Anti-Kickback Provisions, 59 Fed. Reg. 37202 (proposed July 21, 1994)
13. Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute: Final Rule, 64 Fed. Reg. 63518 (Nov. 19, 1999) (to be codified at 42 C.F.R. pt. 1001)
14. Issuance of Advisory Opinions by OIG, 62 Fed. Reg. 7350 (Feb. 19, 1997) (to be codified at 42 C.F.R. pt. 1008)
15. Issuance of Advisory Opinions by OIG, 63 Fed. Reg. 38311 (July 16, 1998) (to be codified at 42 C.F.R. pt. 1008)
16. OIG Press Release materials accompanying 1991 final safe harbor regulations (on file)
17. Press Briefing by Office of Inspector General Safe Harbor Regulations August 6, 1991 (on file)

EXHIBIT 3

18. Pharmaceutical Manufacturers Compliance Program Guidance. 68 Fed. Reg. 23731 (May 5, 2003)
19. Issuance of Advisory Opinions by the OIG, 68 Fed. Reg. 23731 (May 5, 2003)
20. PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE (1982)
21. 42 C.F.R. 414
22. 42 C.F.R. 416
23. OIG OFFICE OF INSPECTOR GEN., OIG FACT SHEET: FEDERAL ANTI-KICKBACK LAW AND REGULATORY SAFE HARBORS (Nov. 1999)
24. OIG Advisory Opinions 98-2, 98-3, 98-5, 99-2, 99-13, 02-10, 06-02, 07-9, 12-02
25. Health Strategies Consultancy LLC, "Follow The Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain," prepared for the Kaiser Family Foundation, Mar. 2005
26. Lewin Group, CMS Review of Current Standards of Practice for Long-Term Care Pharmacy Services: Long-Term Care Pharmacy Primer, Dec. 2004
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28. Special Fraud Alert on Prescription Drug Marketing Practices (August 1994), *reprinted at* 59 Fed. Reg. 65372 (Dec. 19, 1994)
29. *United States v. Shaw*, 106 F. Supp. 2d 103 (D. Mass. 2000)
30. *U.S. ex rel. Walsh v. Eastman Kodak Co.*, 98 F. Supp. 2d 141 (D. Mass. 2000)
31. *U.S. ex rel. Bidani v. Lewis*, No. 97 C 6502, 2001 WL 747524 (N.D. Ill. June 27, 2001)
32. *U.S. ex rel. Bidani v. Lewis*, No. 97 C 6502, 2001 WL1609377 (N.D. Ill. Dec. 14, 2001)
33. *U.S. ex rel. Bidani v. Lewis*, 264 F. Supp. 2d 612 (N.D. Ill. 2003)
34. *U.S. ex rel. Klaczak v. Consolidated Medical Transport*, No. 96 C 6502, 2002 WL 31010850 (N.D. Ill. 2002)
35. *United States v. Carroll*, 320 F. Supp. 2d 748 (S.D. Ill. 2004)

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36. *U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235 (3d Cir. 2004)
37. *United States v. Jain*, 93 F.3d 436 (8th Cir. 1996)
38. *United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20 (1st Cir. 1989)
39. *United States v. Starks*, 157 F.3d 833 (11th Cir. 1998)
40. *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989)
41. *United States v. Greber*, 760 F.2d 68 (3d Cir. 1985), *cert. denied*, 476 U.S. 988 (1985)
42. Tr. of J. Maddox Nov. 4, 2013 Dep., *U.S. ex rel. Banigan v. Organon USA Inc.*, Civil Action No. 07-12153-RWZ (D. Mass.)
43. Tr. of D. Maloney Nov. 6, 2013 Dep., *U.S. ex rel. Banigan v. Organon USA Inc.*, Civil Action No. 07-12153-RWZ (D. Mass.)
44. State Medicaid Fraud Control Unit Subpoena Responses
45. Third Amended Complaint, *U.S. ex rel. Banigan v. Organon USA Inc.*, Civil Action No. 07-12153-RWZ (D. Mass.)
46. United States of America's Assented-To Mot. To Interpose A Statement of Interest in Connection with the Parties' Pending Mot. To Dismiss, *U.S. ex rel. Banigan v. Organon USA Inc.*, Civil Action No. 07-12153-RWZ (D. Mass. Aug. 22, 2011), ECF No. 138
47. Statement of Interest on Behalf of the United States of America in Response to Defs.' Mots. to Dismiss, *U.S. ex rel. Banigan v. Organon USA Inc.*, Civil Action No. 07-12153-RWZ (D. Mass. Sept. 30, 2011), ECF No. 144
48. Brief of Amicus Curiae by Pharmaceutical Research and Manufacturers of America, *U.S. ex rel. Banigan v. Organon USA Inc.*, Civil Action No. 07-12153-RWZ (D. Mass. Oct. 31, 2011), ECF No. 153
49. United States' Statement of Interest in Response to Omnicare Inc.'s Mot. to Reconsider, *U.S. ex rel. Banigan v. Organon USA Inc.*, Civil Action No. 07-12153-RWZ (D. Mass. Aug. 3, 2012), ECF No. 194
50. Mem. of Decision, *U.S. ex rel. Banigan v. Organon USA Inc.*, Civil Action No. 07-12153-RWZ (D. Mass. June 1, 2012), ECF No. 173
51. OMNI-BT01177711: Invoice (dated Nov. 2, 2001)
52. ORG-TX08CID0019783-85: Rebate Report (3Q 2002)

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53. OMNI-BT01124494-608: Rebate Report (4Q 2002)
54. BA-JBET000785-820: Rebate Report (1Q 2003)
55. BA-JBET000835-840: Rebate Report (3Q 2003)
56. BA-JBET000841-852: Rebate Report (4Q 2003)
57. OMNI-BT01125670-84: Rebate Report (1Q 2004)
58. JNJ 001083-1120: Supply Agreement between Omnicare, Inc. and Johnson & Johnson Health Care Systems Inc. (effective Apr. 1, 1997)
59. JNJ 001078-80: Amendment to Supply Agreement between Omnicare, Inc. and Johnson & Johnson Health Care Systems Inc. (effective Feb. 1, 1999)
60. OMNI-MA033998-004: Partnership Agreement between Omnicare, Inc. and Johnson & Johnson Health Care Systems Inc. (effective Oct. 1, 1999)
61. JNJ 0010026-1051: Supply Agreement between Omnicare, Inc. and Johnson & Johnson Health Care Systems Inc. (effective Apr. 1, 1999)
62. JNJ 002617-19: Amendment to Supply Agreement between Omnicare, Inc. and Johnson & Johnson Health Care Systems Inc. (effective Oct. 1, 1999)
63. JNJ 001015-18: Consulting & Services Agreement between Omnicare, Inc. and Johnson & Johnson Health Care Systems Inc. (effective July 1, 2000)
64. OMNI-BT01123304-07: Mem. from D. Maloney to RVPs, T. Bien and J. Holden re Remeron SolTabs (dated Feb. 7, 2002)
65. OMNI-BT00115392: PUR Memo (Feb. 7, 2002)
66. OMNI-BT00115389-90: PUR Memo (Sept. 28, 2001)
67. BA-JBET-000969-82: October 2001 Purchase Agreement between Organon and Omnicare (effective date of Oct. 1, 2001)
68. BA-JBET-000995-1009: February 2002 Purchase Agreement between Organon and Omnicare (effective date of Mar. 1, 2002)
69. BA-JBET-001010-12: Amendment to February 2002 Purchase Agreement between Organon and Omnicare (dated July 2002)
70. BA-JBET-001013: Amendment to February 2002 Purchase Agreement between Organon and Omnicare (dated Oct. 2002)

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71. BA-JBET-001017: Amendment to February 2002 Purchase Agreement between Organon and Omnicare (dated Mar. 2003)
72. BA-JBET-001018: Amendment to February 2002 Purchase Agreement between Organon and Omnicare (dated Apr. 2003)
73. BA-JBET-001024-26: Amendment to February 2002 Purchase Agreement between Organon and Omnicare (dated Oct. 2003)
74. BA-JBET-001027-28: Amendment to February 2002 Purchase Agreement between Organon and Omnicare (dated Jan. 2004)
75. BA-JBET-001029-30: Amendment to February 2002 Purchase Agreement between Organon and Omnicare (dated Apr. 2004)
76. BA-JBET-000494-503: February 1999 GPO Purchase Agreement between Organon and MHA (effective date of Feb. 17, 1999)
77. BA-JBET-000504-05: Amendment to February 1999 GPO Purchase Agreement between Organon and MHA (dated Mar. 1999)
78. BA-JBET-000506-07: Amendment to February 1999 GPO Purchase Agreement between Organon and MHA (dated Apr. 1999)
79. BA-JBET-000515-30: February 2001 GPO Purchase Agreement between Organon and MHA (effective date of Mar. 1, 2001)
80. BA-JBET-000537: Amendment to February 2001 GPO Purchase Agreement between Organon and MHA (dated Sept. 2001)
81. BA-JBET-000535: Amendment to February 2001 GPO Purchase Agreement between Organon and MHA (dated Oct. 2001)
82. BA-JBET-000281-90: February 1999 GPO Purchase Agreement between Organon and GeriMed (effective date of Feb. 17, 1999)
83. BA-JBET-000308-24: February 2001 GPO Purchase Agreement between Organon and GeriMed (effective date of Mar. 1, 2001)
84. BA-JBET-000326: Amendment to February 2001 GPO Purchase Agreement between Organon and GeriMed (dated June 2001)
85. BA-JBET-000331: Amendment to February 2001 GPO Purchase Agreement between Organon and GeriMed (dated Oct. 2001)
86. BA-JBET-000569-82: January 2001 GPO Purchase Agreement between Organon and CPS (effective date of Mar. 1, 2001)

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87. BA-JBET-000428-43: March 2001 GPO Purchase Agreement between Organon and Owen (effective date of Mar. 1, 2001)
88. BA-JBET-000464-78: March 2002 GPO Purchase Agreement between Organon and Cardinal (effective date of Mar. 1, 2002)
89. BA-JBET-000479-81: Amendment to March 2002 GPO Purchase Agreement between Organon and Cardinal (dated July, 2002)
90. ORG-TX08CID0000652-65: March 2000 Purchase Agreement between Organon and APS (effective date of Mar. 1, 2000)
91. ORG-TX08CID0000648-51: Amendment to March 2000 Purchase Agreement between Organon and APS (dated Feb. 2001)
92. ORG-BOS0149465-77: March 2002 Purchase Agreement between Organon and NeighborCare (effective date of Mar. 1, 2002)
93. ORG-BOS0085779-92: March 2002 Purchase Agreement between Organon and NCS (effective date of Mar. 1, 2002)
94. OMNI-BT00115410-13: Amendment to March 2002 Purchase Agreement between Organon and NCS (dated Oct. 2002)
95. ORG-BOS0085779-92: March 2002 Purchase Agreement between Organon and NCS (effective date of Mar. 1, 2002)
96. OMNI-BT0000261059-129: Excerpts from 2001 Edition of Omnicare's Geriatric Pharmaceutical Care Guidelines
97. BA-JBET-000909-18: Feb. 1999 PharMerica Agreement
98. BA-JBET-000934-46: March 2002 Long Term Care Purchase Agreement between PharMerica and Organon
99. BA-JBET-000947-49: Jul. 2002 Amendment to PharMerica Agreement
100. BA-JBET-000950: Oct. 2002 Amendment to PharMerica Agreement
101. BA-JBET-000951-52: Feb. 2003 Amendment to PharMerica Agreement
102. BA-JBET-000953-55: Feb. 2003 Amendment to PharMerica Agreement
103. BA-JBET-000958-60: Oct. 2003 Amendment to PharMerica Agreement
104. BA-JBET-000961-62: Mar. 2004 Amendment to PharMerica Agreement